SEDANA MEDICAL

Pioneering volatile anaesthetic delivery

The Sedana Story – from start-up to stock exchange

Millions of patients per year make up our direct target group

The goal is to confirm efficacy and safety

Inhalation sedation is a potential paradigm shift in intensive care.

ANNUAL REPORT 18

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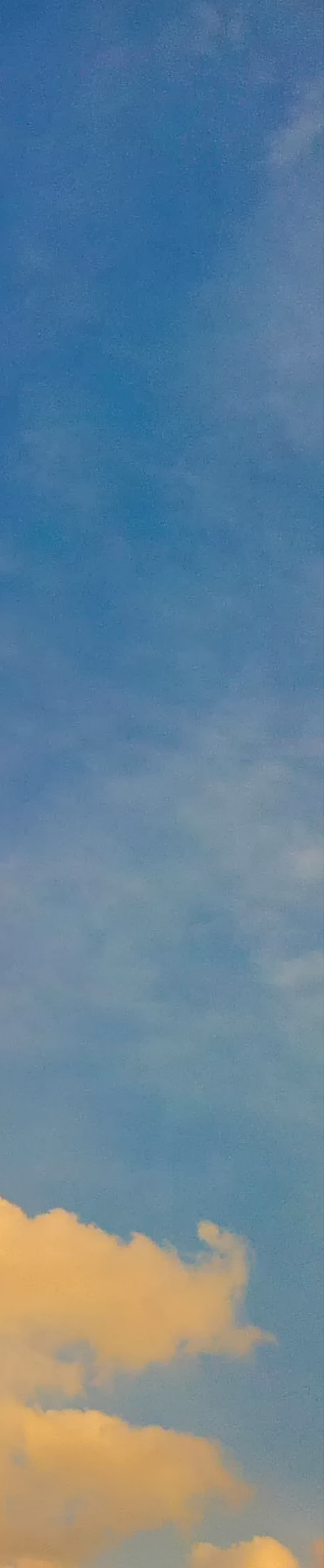
AnaConDa enables inhalation sedation of mechanically ventilated patients in intensive care. AnaConDa administers the volatile drug IsoConDa via the respiratory tract in an efficient, safe, simple, controlled and cost-effective manner.



CONTENTS

FROM DEVELOPMENT COMPANY TO PHARMACEUTICAL COMPANY

ANACONDA IS APPROVED
in Europe for the administration of volatile anesthetics.

3–4

MILLION PEOPLE
every year are sedated for more than 24 hours and on average for 5 days.

Sedana Medical was founded in 2005 in connection with the acquisition of AnaConDa technology. The business has since included in the development of the medical device AnaConDa and its accessories. Sedana Medical has had sales in its test market Germany ever since its founding.

Sedana Medical's vision is to develop inhalation sedation into the standard sedation method of mechanically ventilated patients in intensive care all around the world. Inhalation sedation solves many of the problems that today's intravenous sedation gives rise to.

AnaConDa enables inhalation sedation – the administration of volatile anesthetics via the respiratory tract. This means intensive care can gain access to simple, controllable sedation that is efficient, safe and cost-effective. AnaConDa is approved in the EU. However, because no volatile anesthetic drug is as yet approved for sedation in intensive care units in Europe, Sedana Medical has begun a study as the basis for registering the drug candidate IsoConDa (isoflurane).

The purpose of the study is to obtain marketing authorization for IsoConDa in Europe through AnaConDa for the indication inhalation sedation in intensive care. In Sedana Medical's assessment, it will be the first clinically validated therapy for inhalation sedation in intensive care.

In 2018, Sedana Medical gained market approval for AnaConDa in Japan, and is currently working to enable the company's Japanese distributor to launch AnaConDa in Japan during 2019. As yet, neither AnaConDa nor IsoConDa are approved in the USA, and Sedana Medical has begun planning introduction into the US market by studying and initiating the registration process and investigating the requirement for clinical studies.

30%

SALES

have grown by about 30 percent per year since 2010.

Each year, 15 million people around the world are admitted to intensive care units. Almost half of them need help with breathing by means of a respirator/ventilator. The patients must be sedated in order to endure essential treatment. Around half of these patients – 3–4 million people every year – are sedated for more than 24 hours and on average for 5 days. Based on these figures, Sedana Medical estimates its global market to be SEK 10-20 billion annually and growing as populations age.

Today, Sedana Medical is a development company in the field of medical technology on its way to becoming a pharmaceutical company. The Company conducts R&D in Ireland through its wholly owned subsidiary, Sedana Medical Ltd. Production takes place via contract manufacturers. Its headquarters are in Danderyd, Sweden. In June 2017, the company's stock was listed (ticker: SEDANA) on Nasdaq First North.

In 2018, Sedana Medical achieved sales of SEK 59 million. Sales have grown by about 30 percent per year since 2010. The company has its own sales offices in the Nordics, Germany, France, the United Kingdom and Spain and external distributors in parts of the rest of Europe, Canada, Australia and South Korea. Germany is the company's biggest market.

Sedana Medical's vision is to make inhalation sedation using AnaConDa and IsoConDa the global standard within intensive care.

Own sales offices

Denmark
Finland
Norway
Sweden
United Kingdom
France
Germany
Spain

Sales through distributors

Canada
Belgium
The Netherlands
Israel
Italy
Switzerland
Portugal
Austria
Australia
New Zealand
Japan
South Korea
Romania
Russia
Slovenia

STRONG DEVELOPMENT IN LINE WITH REGISTRATION GOALS

Q1

During the first quarter, Sedana Medical reported a record sales increase of almost 60 percent compared to the equivalent period in 2017. The company's express ambition is to deliver an average annual sales increase of above 20 percent up until the registration of IsoConDa. Germany remains the driving force behind the development of sales, but sales are also trending well in France. Sales resources increased during the quarter, and the company also opened its own sales operations in Norway and Denmark.

Sedana Medical's first global Advisory Board was introduced at an international congress in Brussels – ISICEM. Great interest was shown by the world's medical specialists in the field, including participants from the USA, Canada, Belgium, France and Germany. During the congress, Sedana Medical also made its biggest market investment ever with an exhibition stand and several symposiums, which generated great interest among existing and potential customers.

Q2

A targeted new share issue aimed at institutional investors was carried out in the amount of SEK 112 million. The new share issue was subscribed by e.g. Handelsbanken Fonder, Norron Asset Management, Alfred Berg Kapitalförvaltning, Swedbank Robur and Cliens Kapitalförvaltning. The net proceeds from the new share issue are primarily intended for financing the initiation of the registration process for AnaConDa and IsoConDa in the USA, and to finance and accelerate continued commercialization in Europe.

The inclusion rate for new patients fell temporarily during the quarter as the German central ethics committee queried parts of the inclusion procedure for certain unconscious patients. As a result, the study schedule was extended somewhat.

Sales increased by 52 percent during the quarter compared to the corresponding period in 2017.

Key ratios for the Group

Amounts in SEK thousands (000)	2018	2017	2016
Net sales	57,896	40,428	32,155
Gross profit	42,897	29,662	21,346
Operating profit before depreciation and impairment charges (EBITDA)	-4,232	-736	994
Operating loss (EBIT)	-8,238	-3,488	618
Earnings for the period	-6,869	-3,876	1,286
Gross margin %	74%	73%	66%
EBITDA %	-7%	-2%	3%
Operating margin (EBIT) %	-14%	-9%	2%
Earnings for the period as a % of net sales	-12%	-10%	4%
Balance sheet total	231,550	131,376	23,624
Equity	217,811	116,403	1,262
Equity/assets ratio %	94%	89%	5%
Quick ratio %	1,220%	640%	80%
Average number of employees	26	16	16

NET SALES 2018, SEK THOUSAND

57,896

SALES GROWTH IN 2018

43%

Q3

The clinical registration study in Germany was resumed after the summer and Sedana Medical was able once again to recruit all kinds of mechanically ventilated patients following the limited interruption.

Sedana Medical set up its own sales organization in the United Kingdom with the first sales of AnaConDa in intensive care clinics in Liverpool and Hull. Sedana Medical's ambition is to be represented in many European markets in order to have reference clinicians and a well-established network when IsoConDa is approved and launched.

Sales increased by 24 percent during the quarter compared with the same period for the previous year. While lower than during the first six months due primarily to seasonal patterns, the rate of increase was fully in line with Sedana Medical's ambition of growing by more than 20 percent. There are usually more patients admitted to intensive care units for sedation during the winter. During the winter season and early spring of 2018, this trend was more pronounced than usual with a severe influenza epidemic in major parts of Europe, while the summer was both longer and warmer than usual in many European countries.

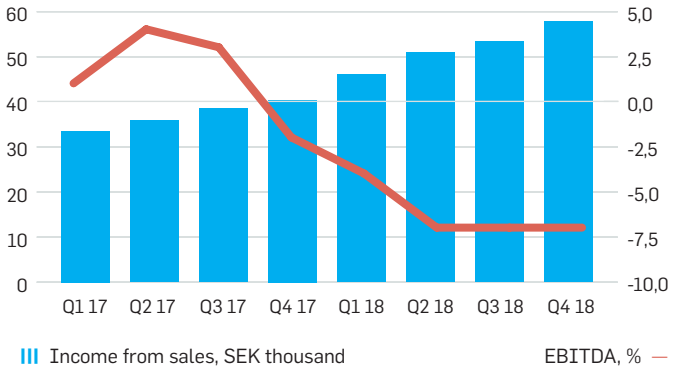
Q4

Sedana Medical obtained market approval for AnaConDa in Japan. Approval means that AnaConDa may be marketed, sold and used for the administration of volatile anesthetic drugs for mechanically ventilated patients in Japan. Sedana Medical is now working to enable the company's Japanese distributor to launch AnaConDa in Japan during 2019.

The company presented a health economics analysis showing clinical and financial benefits of inhalation sedation using isoflurane via AnaConDa compared to conventional intravenous sedation with propofol or midazolam.

The sales increase for the quarter was 41 percent compared to the same period last year. For the full year, we increased sales by 43 percent compared to 2017, which exceeds our ambition about an average increase of 20 percent per year until the registration of IsoConDa in Europe.

Income from sales and EBITDA margin, 12 month rolling



WELL ON OUR WAY TO BECOMING A PHARMACEUTICAL COMPANY

In all, 2018 was a successful year, not least in terms of sales. Sales overall increased by 43 percent compared to 2017, which exceeds our ambition of an average annual 20 percent increase up until registration of IsoConDa in Europe.

Much of the internal work during 2017 focused on making the company administratively prepared for stock exchange listing. The focus in 2018 was on registration efforts for IsoConDa in Europe, AnaConDa and IsoConDa in the USA, and preparing for the launch of IsoConDa in Europe. This manifested itself in a number of ways.

To begin with, I'm pleased to see the organization has begun to find its feet. During 2018, we created a pharmaceutical and clinical development department in order to have the skills necessary for managing the European registration as well as registrations in other countries. Efforts will of course continue moving forward, but work was begun in earnest in 2018.

In parallel with our marketing director taking up her position during the last quarter, we continued developing our sales organization in several countries during the year. We expanded our sales capacity in France, Spain and above all Germany, where we recruited a number of people able to realize Sedana Medical's vision. We also began sales operations in other countries on a smaller scale, in particular Norway, Denmark and the United Kingdom, where we began our own direct sales during the year.

The approval of AnaConDa in Japan during November bears testimony to the excellent in-house registration skills Sedana Medical possesses for medical devices, thus providing a stable foundation upon which to also base our pharmaceutical registration process. We have begun efforts to launch AnaConDa in Japan through our distributor. Thanks to our targeted new share issue in the second quarter of 2018, we were also able to begin efforts to have our therapy approved in the USA.

Our regulatory strategy is based on gaining approval for our medical devices and pharmaceuticals at the same time. Most things are proceeding according to plan regarding registration work for IsoConDa (isoflurane) in Europe. The approval in the new year by the Pediatric Committee of EMA (PDCO) for our planned pediatric study, was most gratifying as this ensures exclusivity in the EU for 10 years. The only setback affecting us during 2018 was the interruption in the clinical registration study, which is now once again proceeding according to plan.

We passed an important milestone on the road to becoming a pharmaceutical company when the health economics analysis was published at the end of the year. It shows the clinical and financial benefits of inhalation sedation using isoflurane via AnaConDa compared to conventional intravenous sedation with propofol or midazolam. To be commercially viable and successful, the therapy must also be accepted as a cost-effective alternative. The health economics study is a good beginning to this process and proof of the therapy's cost-effectiveness. Health economics documentation is necessary to ensure that our proposed price level is approved on the markets in which we intend to launch. The health economics study also shows that the step we have taken into the field of pharmaceuticals is in earnest.

In summary, 2018 was a year in which we took a number of important developments steps and added to our internal skills. We ran our registration efforts, clinical studies and health economics documentation in parallel. While we were working hard to gain approval for the therapy, we were also building a sales and marketing organization with strategic skills for a global launch.

One of the most important steps in our registration efforts was the IsoConDa study, our phase III study as the basis for registration

and approval for the drug candidate IsoConDa (isoflurane) for inhalation sedation in intensive care in Europe. At the beginning of 2019 we received the results from the interim analysis of the study, which I am happy to say showed fewer variations in efficacy than anticipated. The study will therefore only need to include a total of 300 patients instead of the initially estimated 550. This is very positive. We're planning on submitting an application for market approval in the summer of 2020 for 16 European countries. If all goes well, we will have European market approval in the second half of 2021. The interim analysis was an important milestone, and we can now continue with the study at a faster pace.

While 2018 was an eventful year, in many ways, it only marks the beginning of our journey. I look forward to a positive future with excitement!

Christer Ahlberg
CEO and Group President

INHALATION SEDATION IS DEVELOPING INTO THE STANDARD GLOBAL METHOD

Business concept

To provide a solution for many of the problems that today's intravenous sedation gives rise to. Inhalation sedation with the AnaConDa system, which administers the volatile anesthetic IsoConDa via the respiratory tract, enables efficient, safe, simple, controllable and cost-effective sedation for mechanically ventilated patients in intensive care.

Vision

To develop inhalation sedation with AnaConDa and IsoConDa into the standard method for the sedation of mechanically ventilated patients in intensive care.

Financial targets

The company's objective leading up to the approval and registration of IsoConDa, is to increase average annual sales by more than 20 percent while maintaining operating profits before depreciations and impairment charges (EBITDA) without becoming materially negative and while also building up a major sales and marketing organization.

Sedana Medical's ambition is to achieve sales in excess of SEK 500 million (excluding the USA) and an EBITDA margin of 40 percent three years after registration of IsoConDa.

Strategy

The company has created, and abides by, a strategy that can be summarized in three points:

1.

The registration of IsoConDa together with inhalation sedation in Europe

2.

Initiate the registration process for AnaConDa and IsoConDa in the USA

3.

In close collaboration with the market, prepare for an effective, successful launch of the products and the therapy following their registration first in the EU and later in the USA.

THE SEDANA STORY – FROM START-UP TO STOCK EXCHANGE

Sten Gibeck
Member of the Board at Sedana Medical since 2005. Former Board Chairman.

Ola Magnusson
founder and Sedana Medical CEO 2005–2011.

Sten, the technology behind Sedana Medical was originally developed by Louis Gibeck AB, a company you owned and were the CEO of. Tell us a little bit about how it all started.

The Louis Gibeck company had developed heat & moisture exchangers and bacteria filters which it sold to hospitals in many parts of the world. The beginning of the 90s saw the arrival of expensive anesthetics (sevoflurane) onto the market and expensive, complicated anesthetic devices were developed in this context. Because our company was able to reflect heat and moisture, we asked ourselves if it would be possible to reflect anesthetic gas. This would make anesthetic devices much simpler, cheaper and safer for the patient. After much searching and a great deal of experimentation we found a material that worked. It was a special formulation of activated charcoal that reflected 90 percent of the exhaled anesthetic gas without reflecting carbon dioxide. We developed a prototype that went by the name of the Reflector, but when we came to patent it we discovered that an anesthesiologist in Lund had already developed something similar. It was nowhere near as efficient but had been granted a patent, and when we visited the physician concerned we were in luck, as he was willing to sell the patent to us. Our initial focus was to develop an entirely new anesthetic system and we came as far as a prototype for an entirely new anesthetic device which was also tested on pigs and later successfully on patients.

Ola, you were Sedana Medical's CEO from 2005 to 2011, and before that you were CEO for Louis Gibeck.

I began as CEO for Louis Gibeck in March 1996, and one of my main assignments was to take the company public, and in December 1997 we were listed on the stock exchange. Back then, Louis Gibeck was not at all focused on AnaConDa, or the Reflector as it was called then, and if truth be told the AnaConDa project was almost a source of irritation. Because it cost a great deal of money, it was given low priority. Louis Gibeck was a company with an international product line and there was no intention to develop new, highly innovative products. Following Gibeck's listing on the stock exchange, development of the Reflector/AnaConDa continued and despite its low priority we made sure the product was tested clinically and a study was carried out at Samariterhemmet in Uppsala.

But Gibeck was later sold to Hudson RCI; what happened to AnaConDa then?

STEN: Gibeck was sold to the American company Hudson RCI in December 1999. Development on the Reflector continued. Because we had an intact development department in Sweden we were able to continue work, but we received a lot of feedback from intensive care physicians that led us to our new focus on sedation within intensive care. Our decision to change direction was based largely on a clinical study published in the renowned journal Critical Care of Medicine in November 2004, which compared isoflurane administered with AnaConDa to midazolam. The study was carried out by Peter Sackey, who is now chief medical officer (CMO) at Sedana Medical. Peter conducted several studies with isoflurane and these resulted in a doctoral thesis in 2006 entitled Inhaled sedation in the intensive care unit.

The new direction was good for a number of reasons. It did not require any expensive investment for the development of a new anesthetic device, and even more importantly, we would

probably be able to sell the Reflector – which had now been given the new name AnaConDa (Anesthetic Conserving Device) – at a significantly better price.

OLA: AnaConDa was an odd story also at Hudson RCI, but despite this it was developed further and became a CE marked product in 2003. We then began to investigate how the market looked. We looked at Sweden, Germany and France and took contact with distributors in all of these markets who had expressed an interest in selling AnaConDa.

But in 2004, Hudson RCI was sold to a major conglomerate, Teleflex.

STEN: It very soon became apparent that our exciting project was also utterly uninteresting for Teleflex, but around this time we presented AnaConDa for the first time at a European intensive care conference, and it generated a great deal of interest.

OLA: We were present at two exhibitions. One in Amsterdam 2003 – ESCIM – and one in Paris in 2004, the World Congress of Anaesthesia. The interest was overwhelming. We were unable to accommodate all of the interested parties. Our stand covered a relatively large area, but it was constantly full. Completely new, innovative products are rare, and many physicians were taken aback when we described how the product worked.

And so you founded Sedana Medical?

OLA: We had been given such a magical reception at the exhibitions that we informed Teleflex we wanted to buy out the AnaConDa technology. To pull this off we – Sten and I – partnered with an Irish conglomerate and a small pharmaceutical company known as Pharmalink. The transaction was concluded in time for new year 2005, and early in January I rented a truck and picked up everything that had to do with AnaConDa and drove it to our new office. It soon became apparent that these were early days, and the road leading to general acceptance proved to be a long one. There was a great deal of interest and we met many so-called early adopters who later helped us make headway with development.

So, setbacks once again; how did you manage to move forward?

STEN: We contrived to get things moving in Germany, but it was heavy going. We had many problems. The therapy requires a gas analyzer and it took a long while for us to find a good supplier and a business structure. However, interest was so great that several clinics in Germany conducted clinical studies that showed good results for patients, and the studies were presented at various seminars. What's more, the study showed that only insignificant quantities of anesthetic gas made their way into the environment, which was important for winning over intensive care nurses. The breakthrough

Sedana Medical's history in brief

1999
AnaConDa was used for the first time in Sweden in the middle of the 1990s and was tested clinically for the first time

2005
Sedana Medical founded in Uppsala
Sedana Medical opens an office in Germany

2007
Sedana establishes a test market in Germany

2008
Studies show that short-term sevoflurane sedation and AnaConDa following heart and thoracic surgery result in significantly shorter ventilation times and hospital stays.

2012
New sales office opens in Madrid, Spain

2013
New R&D laboratory opens in Kildare, Ireland

came in 2009 and 2010 when the German Society of Anesthesiology and Intensive Care Medicine began describing inhalation therapy as an alternative to intravenous sedation in its recommendations.

However, the biggest problem was the fact that isoflurane, the anesthetic gas used, was not registered for use in ICUs. As such, it was off-label use where we were not allowed to actively market the therapy and physicians themselves took responsibility. As a result, we began extensive efforts led by Ola to draw up a protocol for clinical studies and took contact with the German Federal Institute for Drugs and Medical Devices (BfArM) to see how we should proceed.

OLA: When we contacted BfArM and told them we wanted to register the drug, they asked us: "Why don't you talk to a proper pharmaceutical company?" Well guess what, we'd already talked to them all, but none of them was willing to bother with it because it concerned generics. Instead we asked the BfArM if it was interested in helping us through the process since isoflurane was already used a great deal off label. They were willing, but it would take money.

Is that why you listed Sedana Medical on the stock exchange?

STEN: Yes. There was no more money. As partners, we still believed in the project and tried to find a number of alternative solutions but no one wanted to invest in a project that was dependent on a drug that was not registered. For example, in order to save money and establish an organization we had consolidated our head office to Ireland. We now drew up a plan that would cost between SEK 50 and 75 million to realize, but we had neither the organization nor the financial resources, and my energy as chairman of the board began to wane.

The best decision I took was to step down from my chairmanship. I'm quite happy to say that recruiting a professional chairman – Thomas Eklund– was one of the most important strategic milestones in Sedana Medical's journey. He played a crucial part in bringing Sedana Medical to where we are today, and after many exciting board meetings we resolved to carry out an IPO.

OLA: I've always believed passionately in AnaConDa, and in a small company passion is extremely important, but now that Sedana Medical has become so big and taken on so many capable people I mostly try to keep my hands off. We're obviously both delighted that thousands of patients have already been sedated and enjoyed the benefits of AnaConDa since we began.

The IPO

STEN: Everything fell into place thanks to all the hard work and the board's and the chairman's networks. In the beginning of 2017, we moved the head office from Ireland to Sweden, a new energetic CEO was recruited and the company was listed on First North Stockholm the week before Midsummer 2017. The listing brought in SEK 115 million to the company and in June 2018 we carried out a new share issue that added a further SEK 112 million, which will take us into the American market.

2014

AnaConDa is now used in Canada, Australia and most of Europe.

2015

Studies show one-year mortality to be significantly lower in patients given isoflurane compared to intravenously sedated patients.

2016

Over 200,000 units have been used since the launch

2017

- Christer Ahlberg appointed new CEO
- KFDA approves AnaConDa in South Korea
- New AnaConDa-S launched in Europe
- New head office opens in Stockholm
- The company is listed on Nasdaq First North
- IsoConDa study begins

2018

- Opened our own sales offices in the UK and the Nordics
- AnaConDa received market approval in Japan
- Health-economics study shows the benefits of AnaConDa

MILLIONS OF PATIENTS PER YEAR MAKE UP OUR DIRECT TARGET GROUP

Sedana Medical's market consists of sedated and mechanically ventilated patients in intensive care units all over the world.

Every year, around 15 million patients are admitted to intensive care units around the world. Many of them are in extremely critical condition, making breathing support by means of a respirator necessary. This type of support is usually referred to as mechanical ventilation, and of the total number of patients admitted to intensive care units, between 30 and 50 percent are ventilated mechanically.

Mechanical ventilation is an unpleasant experience and for patients to endure it, they must be sedated to mitigate tension, anxiety and pain. Sedation is also necessary if staff are to be able to carry out the treatments required.

Narcotics such as benzodiazepines and propofol are used for the sedation of mechanically ventilated patients today. They are given intravenously and while they have well-known advantages there are also a number of disadvantages, both for healthcare and for the patients.

Inhalation sedation is best suited for patients who will be ventilated for more than 24 hours, which is around 50 percent of them. Thus between 2 and 4 million patients per year make up the direct target group for AnaConDa. On average, these patients are ventilated for five days, which adds up to between 10 and 20 million days under sedation. The cost of sedation using IsoConDa and AnaConDa is estimated at around SEK 1,000 per day, giving a total market valuation of between SEK 10 and 20 billion.

50%

INHALATION SEDATION
is best suited for patients who will be ventilated for more than 24 hours, which is around 50 percent of them.

SEK

10–20

BILLION
The cost of sedation using IsoConDa and AnaConDa is estimated at around SEK 1,000 per day, giving a total market valuation of between SEK 10 and 20 billion.

80%

of all mechanically ventilated intensive care patients are affected by delirium, and the annual cost of managing intensive care patients with delirium is between USD 4 and 16 billion in the USA alone.

> **Sedana Medical is well positioned to offer the first commercial solution** for inhalation sedation within intensive care, a market with an annual sales potential of SEK 10–20 billion."

Because the problems with intravenous sedation are less evident for sedation during shorter periods, intravenous sedation will continue to play a significant role. For extended periods, the shortcomings of intravenous sedation are greater, and there is a major need for alternative methods.

The target group for the company's products are intensive care physicians, intensive care nurses and decision-makers with the responsibility for purchasing medical equipment and pharmaceuticals for these departments.

The competitive situation

The current market for sedation drugs in intensive care consists only of intravenous drugs. The company assesses the total annual size of this market to be around SEK 20 billion where propofol, midazolam (based on benzodiazepine), dexmedetomidine and remifentanil predominate. These drugs are usually generic and marketed at low prices with the exception of dexmedetomidine, which costs around SEK 1,400 per patient per day in Europe.

The company believes propofol to have more than half the market and that drugs based on benzodiazepine have the next largest market share, but that benzodiazepines are losing market share to propofol and dexmedetomidine. Problems with tolerance development and delirium such as hallucinations and delusions have caused many physicians to advise against benzodiazepines for long-term sedation.

Costs

At an average cost of between SEK 10,000 and 30,000 per patient day, intensive care patients are expensive. The cost of an intensive care unit is 3 to 5 times higher than an ordinary hospital ward, and despite the fact that these patients only constitute around 10 percent of all hospital admissions, they can consume closer to 20 percent of a hospital's total budget.

Thus there are compelling financial reasons for hospitals to reduce the number of ICU treatment days. What's more, Sedana Medical considers intensive care clinics to be relatively price insensitive in respect of sedation drugs as they constitute a relatively small part of the total cost of healthcare.

"The benefits of using inhalation sedation are becoming increasingly apparent as populations age and intensive care units admit growing numbers of elderly patients."

The daily cost for intravenous sedation is difficult to estimate and varies greatly from country to country. The cost calculation is made more difficult since different preparations are often combined (e.g. propofol and midazolam) to achieve the desired effect and because dosages may vary depending on the patient's tolerance of the preparation. The great number of factors means that the cost of intravenous sedation can range between SEK 200 and 3,000 per day.

Sedana Medical in Germany

In 2010, new guidelines for the use of sedation were published in Germany. The guidelines put forward inhalation sedation and the use of isoflurane as an alternative to intravenous sedation in intensive care for certain patient groups. The new guidelines together with positive statements from a number of key German opinion leaders (KOLs) have led to extensive use of AnaConDa in Germany. The company estimates that more than 500 intensive care clinics around Germany use AnaConDa. With the aid of AnaConDa, these clinics have sedated mechanically ventilated intensive care patients for a total of around 400,000 days. The use of AnaConDa in Germany during 2018 represents around 5 percent of the total market potential. Between 2006 and 2018, Sedana Medical sold more than 300,000 AnaConDa units in Germany alone, and the company shows continued good growth.

"Sedana Medical's principal target group comprises mechanically ventilated intensive care patients sedated for periods longer than 24 hours."

Costs in the USA are significantly higher and Sedana Medical estimates average costs to be around three times higher than in Europe.

Sedana Medical estimates the average cost for intravenous sedation in Europe to be around SEK 600 per day, which is somewhat lower than the daily cost of AnaConDa and isoflurane. The cost of sedation using IsoConDa and AnaConDa is calculated at around SEK 1,000 per day.

In November, Sedana Medical presented a health economics analysis showing clinical and financial benefits of inhalation sedation using isoflurane via AnaConDa compared to conventional intravenous sedation with propofol or midazolam. It was presented at the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Europe 2018 congress in Barcelona.

Market drivers and trends

Sedana Medical notes five principal trends that affect underlying market growth:

- Increased awareness of the risks of delirium
- Reduced use of benzodiazepines
- An aging population
- The need to reduce the cost of healthcare
- The benefits of lighter sedation

Increased awareness of the risks of delirium

The number of scientific studies examining the occurrence of delirium in intensive care patients has increased considerably over the past decade, and delirium has been recognized as a growing public health problem in the USA. Delirium affects up to 80 percent of all mechanically ventilated intensive care patients, and the annual cost of managing intensive care patients with delirium is between USD 4 and 16 billion in the USA alone.

Reduced use of benzodiazepines

Several studies show that benzodiazepines used for extended periods can lead to a number of undesirable clinical outcomes. Extended periods under ventilation, increased time in the intensive care unit and the occurrence of delirium are

some of the undesirable effects linked to the use of these drugs.

An aging population

There is an underlying global trend, especially in Europe and the USA, toward an aging population. In Europe, the number of people over 65 is expected to rise from 16 percent in 2010 to 27 percent in 2050[1]. Elderly people in general are in poorer health with a lower ability to recover after an operation or serious injury, which means senior citizens who end up in intensive care tend to remain longer than young people.

The need to reduce the cost of healthcare

The costliest beds in a hospital are those occupied by intensive care patients, and thus there are compelling incentives to shorten intensive care stays instead of increasing the number of intensive care beds. Seen in the light of an aging population and an average life expectancy that is anticipated to go on rising, costs for healthcare in general and intensive care in particular are also expected to continue rising.

The benefits of lighter sedation

A broad and growing corpus of medical literature shows that lighter sedation is beneficial for patients when they are able to breathe unaided and who are woken daily to allow vital signs to be checked. Inhalation sedation with AnaConDa is a very suitable solution as the dosage is easy to adapt.

Facts about sedation

Sedation drugs is a collective term for tranquilizing and sometimes analgesic drugs used in many healthcare areas. Sedation means putting a patient into a medically induced state of reduced consciousness to relieve anxiety, tension and pain, usually by intravenous means. The sedation of patients who are ventilated mechanically with the aid of respirators often continues for extended periods, usually between four and nine days. Intensive care is one of the principal areas of application for sedation, where it represents one of the more common therapies.

The concept of sedation encompasses a range of consciousness levels and a number of different scales are used to measure them. For the sake of simplicity, a three-level scale defined by the American Society of Anesthesiologists is used here.

- **Minimal sedation** – mitigates anxiety and induces a relaxed state. The patient is fully conscious without any impact on bodily functions.
- **Moderate sedation** – induces a lower level of consciousness, but the patient still responds when touched or addressed. Airway reflexes, breathing and cardiac function are kept intact.
- **Deep sedation** – the patient is beyond consciousness but responds to repeated pain stimuli. Cardiac function is maintained, but airway reflexes and breathing may be impaired.

A concept known as general anesthesia is one level deeper than deep sedation and is used in conjunction with surgery.

General anesthesia is a collective term for a number of methods that use drugs to render a patient deeply unconscious and so oblivious to pain that surgery can be performed. The patient does not respond to any form of stimulation but is so deeply sedated that respiratory assistance is necessary. During general anesthesia, an anesthesia machine is used where a preparation is administered according to current practice through inhalation, or in some cases intravenously.

A CLINICIAN IN LOVE WITH THE THERAPY

Currently, sedating mechanically ventilated intensive care patients is done intravenously, which entails injecting the tranquilizer directly into the bloodstream with the aid of a cannula. The drugs used are well-established but are burdened by a number of well-known medical problems that can be harmful for the patient and impair care.

Dr. Kerstin Röhm is a physician and an early user of Sedana Medical's equipment. She is the head of the intensive care unit at St Mary's hospital in Ludwigshafen, Germany.

Can you tell us a little about your experience in sedation? I've worked as a physician in intensive care since 2004. I also worked in intensive care in 1993 during my studies, so I've seen every imaginable problem with intravenous sedation. Previously, it was the only available form of sedation and problems were especially common with midazolam, the substance that was the trendiest back then.

When was your first contact with Sedana Medical? I saw AnaConDa for the first time purely by chance at a congress for intensive care and emergency medicine in 2006, ISICEM in Brussels. Back then, Sedana Medical had a very small stand where CEO Ola Magnusson and Sales Director Robert vom Dorp presented AnaConDa. Robert is now Global Sales Director at Sedana Medical, but in those days Ola and Robert were practically the entire company. But from that moment on, I was in love with the therapy.

I wrote my doctoral thesis on inhalation sedation in intensive care and I was the first to organize a symposium on inhalation sedation in Germany. Since then I've been invited to attend many congresses in Europe to present my extensive experience of inhalation sedation, and I've also conducted a number of studies. But my main work over the past 18 years has been with patients at the clinic.

Sedana Medical has really developed since the first time you met; can you describe the journey? As I see it, Sedana Medical has successfully established a concept for sedation in the field of intensive care. The company has combined scientific effort with active support for practical use within intensive care while also continuing to develop the medical product. And it was not only safety reasons that led to changes in the product (e.g. a special Luer-Lock that makes AnaConDa incompatible with intravenous use), but development of AnaConDa-S has opened up a broader field of use.

What are the problems with intravenous sedation? It's difficult to monitor, control and adjust the depth of intravenous sedation, which often leads to unnecessarily high drug doses. When it's time to wake the patient, it can take a long time – sometimes days. Because of accumulation and active metabolites, this can also happen in patients who have received the

correct dose. What's more, some patients can develop a tolerance to sedation, which means the drug becomes less effective over time and the dose must also be increased for that reason. This then requires sedation by a number of different drugs, but because the mixture has not been investigated particularly well in studies, it is unclear how it will affect the patient. It's not possible to know if there will be an interaction between the drugs, or how long the patient will remain asleep. As a result, undesirable side effects can prolong ventilation time and the hospital stay.

The breakdown and excretion of preparations administered intravenously takes a long time; what does this mean for the patient? Drugs are metabolized chiefly by the liver and/or the kidneys, and for drugs to function properly, the patient must have a well-functioning metabolism, but in elderly patients organ function is often impaired. Many patients have a slower drug metabolism and reduced kidney function. This means that elimination time – the time it takes for a drug to be broken down and leave the body – is longer and that such patients require cautious treatment. When drugs accumulate, sedation can last longer and when drugs are not eliminated quickly, doses become difficult to tailor.

Intensive care patients around the world are getting older; what does this mean? I've worked in intensive care clinics for many years, and these days people admitted are often over 90 years old. They have cardiac insufficiencies, cardiovascular problems, liver insufficiency and often intestinal problems. We try to avoid drugs that could aggravate these problems. Elderly patients are often very sensitive to opioids and may suffer from respiratory depression. The elderly are also at much greater risk of delirium. When drugs are not eliminated and last longer, there is a greater risk of cognitive disorders. There is a clear link between the use of intravenous sedation and delirium, which is one of the most important causes of increased mortality among intensive care patients.

Will intravenous sedation disappear?

No, inhalation sedation will certainly increase, but intravenous sedation will continue to be used frequently in intensive care. The advantages of inhalation sedation are not as great in short-term sedation as they are over longer periods. It's also a matter of habit; almost everything we do in intensive care takes place intravenously, and in some cases we even provide nourishment in this way. Thus it would be unrealistic to believe that intravenous sedation will not continue to be common. Propofol in particular is here to stay. In the case of sedation for short periods (less than 24 hours) the problems are not as pronounced, and intravenous sedation will continue to be used a great deal. The shortcomings are greater in sedation over longer periods and there is a major need for better alternatives such as inhalation sedation.

What properties would you like to see in a sedation drug? I would like to see sedation that is predictable and preferably with a short duration so that patients can be brought round quickly. Sometimes a drug has a good primary sedation effect, but at the same time it produces an active metabolite that is not possible to control, thus delaying awakening significantly, sometimes by days. A drug without active metabolites would be preferable, and one free from dependency and withdrawal problems would be good. Most of these problems can be solved with inhalation sedation.

What do you like most about AnaConDa?

The beauty of AnaConDa is that I only need one drug for light and deep sedation alike. A drug that is easy to tailor and which can be used both in the acute phase of a critical illness and at later stages. Also, it breaks down so quickly that I know my patients can be woken within a few minutes, letting me know when I can start working with them. It also makes things easy for me as an anesthesiologist as I'm using the same drug I'm accustomed to using in the operating room, and I just need to reduce the dose – usually by half – so it's extremely easy for me to manage inhalation sedation, in particular with AnaConDa.

What obstacles do you foresee for Sedana Medical when it comes to commercializing AnaConDa? Over the years I've learned that much depends on the chief physician in the intensive care unit. If the person is open for change and ready to try innovations, things can begin to happen. But we also need the support of the nurses if new therapies are to have an impact. Making changes usually takes more than a year in an intensive care unit. I believe it will be a lot easier for Sedana Medical to get a foot in the door when IsoConDa is no longer an off-label product. Spreading the therapy around the world will be much easier then.

AnaConDa – ANESTHETIC CONSERVING DEVICE

AnaConDa is a unique, innovative product that enables the safe, simple administration of volatile anesthetics, which was not previously possible without an anesthesia machine.

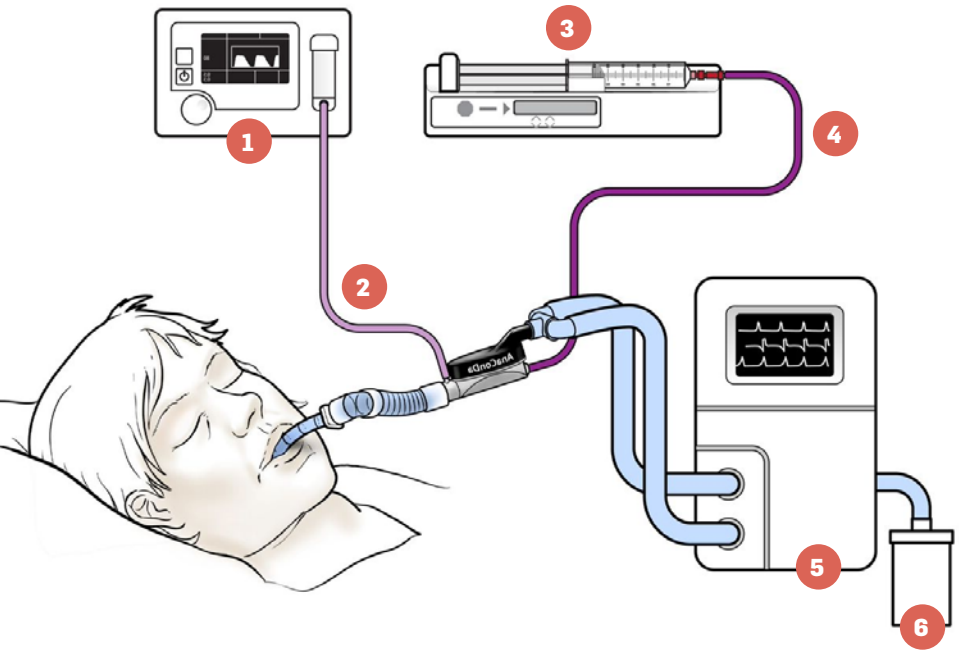
AnaConDa (Anesthetic Conserving Device) is an anesthetic delivery system developed for the administration of volatile anesthetics such as isoflurane or sevoflurane to mechanically ventilated patients.

AnaConDa is a less complicated alternative to an anesthesia machine. It is intended for single use and must be replaced every 24 hours. AnaConDa is a small device that is inserted in the respiratory tract between the ET-Tube and the Y-piece AnaConDa's design incorporates a unique miniature vaporizer and a reflector that enable the simple, safe and efficient delivery of anesthetics. AnaConDa works with all types of ventilators and syringe pumps and delivers volatile anesthetics as effectively as an anesthesia machine.

AnaConDa is designed to be simple to use and to work together with all modern intensive care ventilators, syringe pumps and gas monitors. For most hospitals, this means they can avoid expensive new investments.

COMPATIBLE WITH ALL VENTILATORS, SYRINGE PUMPS AND GAS MONITORS

1. Gas monitor or module
2. Measuring line
3. Syringe pump
4. Agent line
5. Ventilator
6. Passive or active scavenging system



AnaConDa-S

The original AnaConDa version (100 ml) is aimed at adult intensive care patients. In a continued development of the technology, Sedana Medical launched a new improved version of AnaConDa – AnaConDa-S – in March 2017 in which the so-called dead space was halved from 100 ml to 50 ml. The reduction in dead space means that AnaConDa can now be used on patients who for various reasons have lower lung volumes than a typical adult, e.g. children or patients who have reduced lung capacity due to illness. The company estimates that this improvement has led to an increase in the AnaConDa target group by around 25 percent. Because healthcare in general seeks to reduce dead space in all patients, the company estimates that the new 50 ml version will dominate the market moving forward.

The technology

Sedana Medical's unique, patented Anaconda technology combines the four functions incorporated in anesthesia machines in one single unit: a gas evaporator (required for the controlled production of the anesthesia gas), the reflector with a unique activated charcoal filter (for recir-

culating and conserving the anesthesia gas), a bacteria filter and a heat & moisture exchanger. The technology enables very efficient reflection of anesthesia gas from expiration air; more than 90 percent of the gas remains in the active charcoal filter and is re-used during the inspiration phase. This high level of reuse not only helps reduce the consumption of volatile anesthetics, but also the spread of gas to the surroundings, and studies confirm that AnaConDa has very low emissions and is safe to use in intensive care clinics.

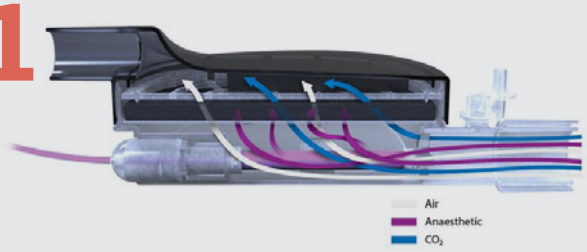
AnaConDa provides the same functionality as conventional anesthesia machines but in a very compact format and without the need for a major investment or expensive operating staff. Thanks to its unique technology, AnaConDa provides a simple, effective way to make inhalation sedation the new standard for the sedation of intensive care patients.

How does AnaConDa work?

AnaConDa is used in combination with a ventilator, a gas monitor and a syringe pump. The specially designed AnaConDa syringe (unique connector) is placed in a standard syringe pump. AnaConDa is placed in the breathing circuit between the Y-piece and the ET-tube Liquid anesthetic is delivered from the syringe through the agent line to AnaConDa where it is vaporized inside the device. The evaporated gas is transported with the inspiration flow from the ventilator and delivered to the patient. The gas monitor samples the gas from the AnaConDa port and displays the exhaled concentration of anesthetic in Fet% or MAC values (which indicate drug concentration).

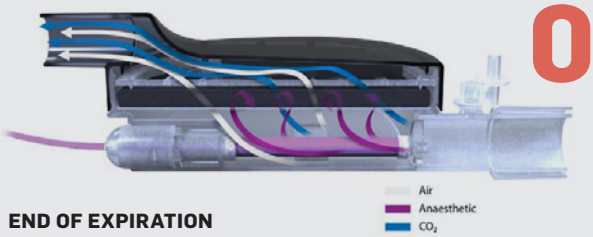
Thanks to AnaConDa's unique design, most of the exhaled anesthetic is adsorbed by the charcoal filter, released and returned to the patient upon inspiration. The residual anesthetic passes through the ventilator, out through the exhaust where it is captured in the FlurAbsorb filter or active gas scavenging system.

01



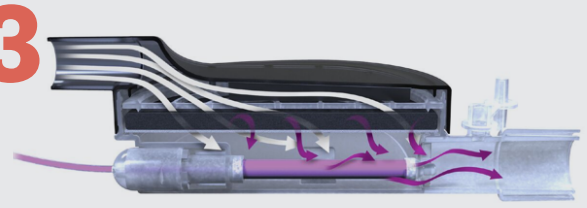
START OF EXPIRATION
At the start of expiration, expiration air contains CO_2 and the volatile anesthetic.

02



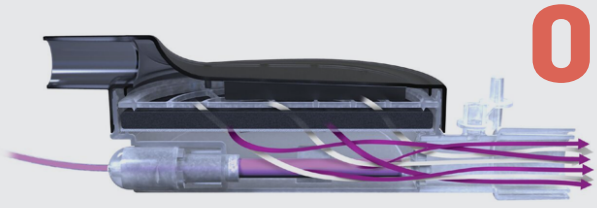
END OF EXPIRATION
Air/oxygen and CO_2 pass through the active charcoal filter while the majority of the volatile anesthetic is adsorbed by the activated charcoal filter. Next, expiration air (almost exclusively air/oxygen and CO_2), passes out through the ventilator tubing and then through the ventilator outlet.

03



START OF INSPIRATION
When inspiration begins, air is carried from the ventilator and passes through the AnaConDa unit.

04



END OF INSPIRATION
During inspiration, anesthetic retained in the reflector is released from the activated charcoal filter into which it was previously adsorbed during expiration, and transported together with air/oxygen to the patient. New anesthetic is constantly evaporated in the mini-evaporator.

IsoConDa

IsoConDa is Sedana Medical's brand name for the drug isoflurane.

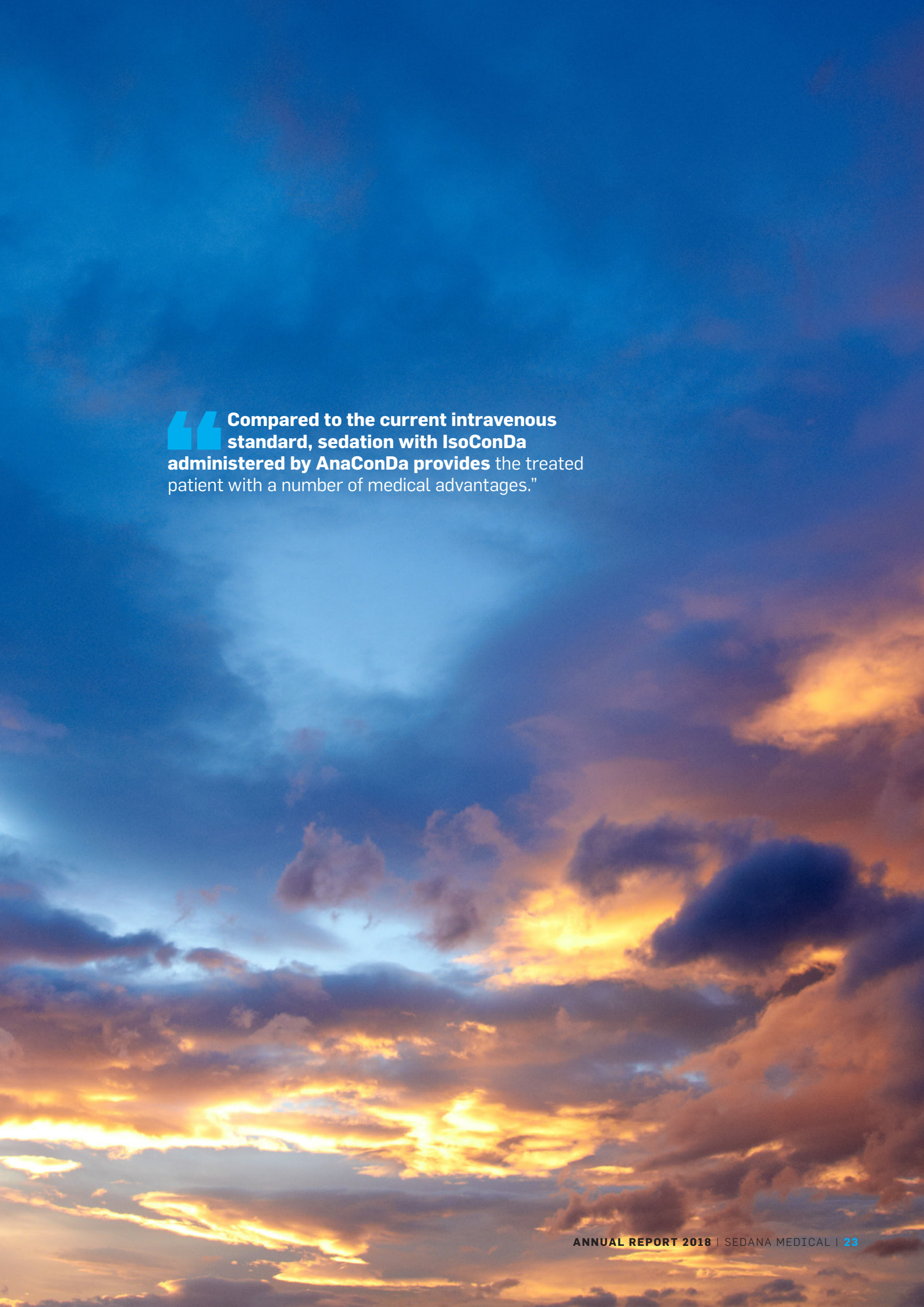
Isoflurane is a volatile anesthetic that should be used in conjunction with AnaConDa to reach its full potential. IsoConDa is currently not marketed as this cannot take place until marketing authorization is obtained. Today, there are clear recommendations advising against the use of benzodiazepines for sedation within intensive care, but the alternatives are limited. It is Sedana Medical's firm belief that IsoConDa is able to fulfill this role.

Compared to the current intravenous standard, sedation with IsoConDa administered by AnaConDa provides the treated patient with a number of medical advantages, of which some are listed below:

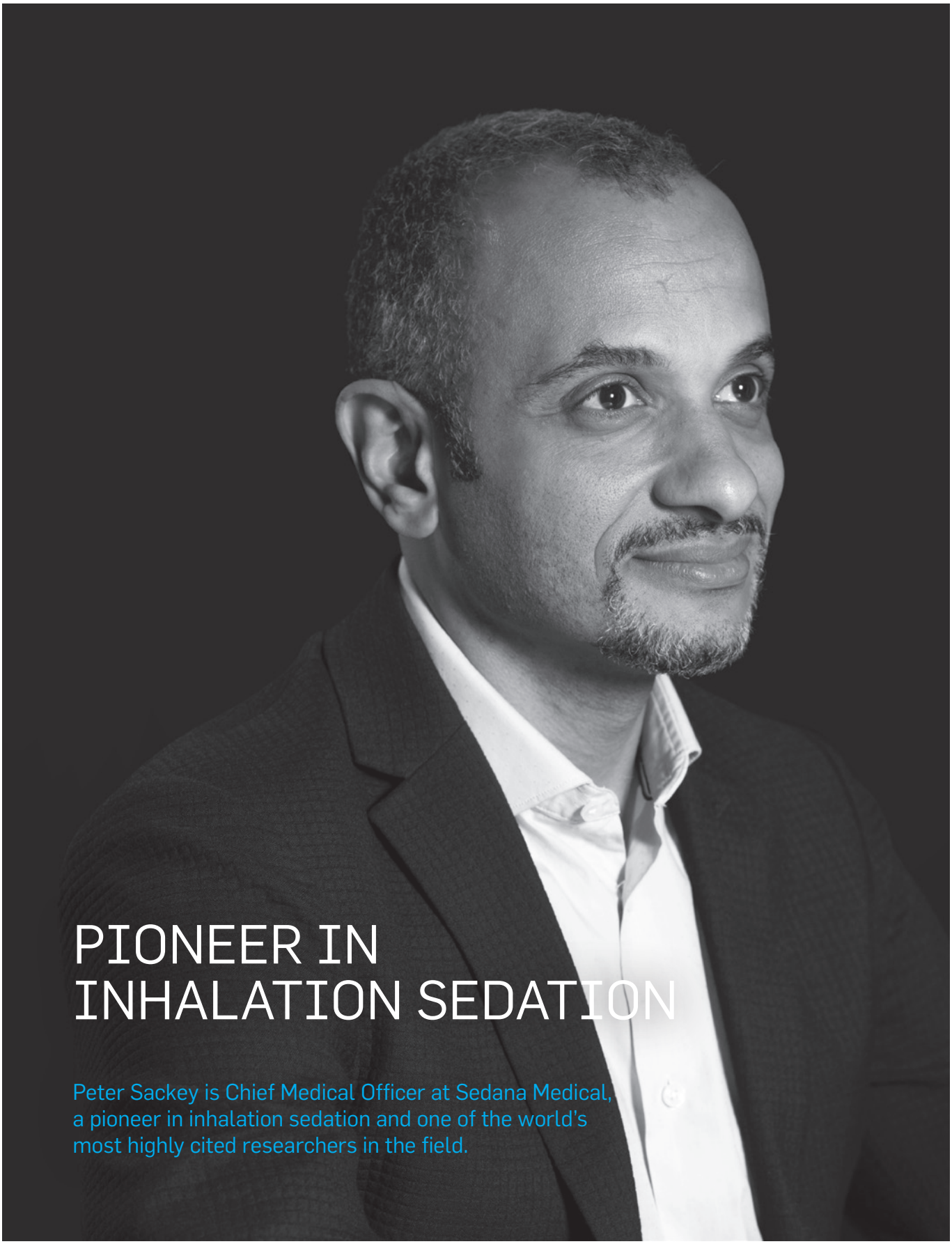
- **Shorter wake-up times.** When treatment is complete and it's time to wake the patient up, it's important that the patient is lucid and cooperative as soon as possible. It also makes it easier for staff to plan their work.
- **Easier to control sedation levels.** It's easier to wake patients every 24 hours to check their neurological status and reduce the need for additional CT examinations.
- **Can be used by patients with kidney and liver disease.** Isoflurane is administered and excreted via the lungs with minimal breakdown in the body.
- **Organ-protective characteristics.** Inhalation sedation has potential protective cardiovascular, respiratory and nervous system characteristics.
- **Bronchodilator effect** Improves lung function in patients with COPD, ARDS, asthma and other respiratory diseases.
- **Reduced need of analgesic drugs** (opiates). When Isoflurane is used, the analgesics (opiates) dose can be reduced by more than 35 per cent. Opiates cause problems for the elderly in getting their bowels to move after treatment. Clinical studies indicate that mortality rates are reduced, the frequency of delirium tends to fall and that treatment times in intensive care are shortened.

Product accessories

In addition to AnaConDa and IsoConDa, various accessories are also marketed to facilitate and simplify the use of AnaConDa. These include syringes to supply AnaConDa with isoflurane, special adapters to connect syringes to AnaConDa and the FlurAbsorb filter used to clean and remove any volatile anesthetic emitted into the intensive care room when sedating with AnaConDa.



“Compared to the current intravenous standard, sedation with IsoConDa administered by AnaConDa provides the treated patient with a number of medical advantages.”



PIONEER IN INHALATION SEDATION

Peter Sackey is Chief Medical Officer at Sedana Medical, a pioneer in inhalation sedation and one of the world's most highly cited researchers in the field.

Peter, you took up your post as Chief Medical Officer in January 2018, but you have a long background with Sedana Medical; tell us about the first time you came in contact with the company.

I was in the middle of a study to test the first AnaConDa prototype when the company was formed. I was a doctoral student and it was my first study as a researcher at the central intensive care unit at the Karolinska University Hospital. The simple method of administering anesthetic gas for sedation sounded like an attractive idea, and the outcome of our studies made me even more convinced that this treatment really had a future.

Tell us a little about your experience in sedation.

The sedation of intensive care patients has been one of my specialist fields over the past 15 years. Patient who receive intravenous benzodiazepines often wake up with delirium after sedation. They can be very confused and worried, and many also suffer from unpleasant hallucinations and nightmares. In my thesis, which discussed sedation using isoflurane, patients who had been sedated with isoflurane had fewer such problems. It's often possible to talk to patients just one hour after sedation with isoflurane. Other, later studies have also borne out our findings that patients' recovery and experiences after inhalation sedation are better than after intravenous sedation, which leads me to believe even more in this therapy. To date, almost 100 studies concerning AnaConDa and inhalation sedation have been published. Based on my own experience and the science available today, I am perfectly sure that isoflurane would be my first choice were I to be intubated for sedation in an intensive care unit.

What brought you to begin working at Sedana Medical?

I have long believed in the therapy, ever since my first studies in the field. A decade of data relating to inhalation sedation pointed in the same direction as my results and experience. I enjoy challenges, and when Sedana Medical decided to conduct the studies necessary for European approval, I felt an eagerness to help establish inhalation sedation as the standard global method. I guess in some way pushing this forward to approval seems the responsible thing to do, not just to get the therapy established, but also so that follow-up is done "by the book".

What are you most proud of so far in your journey with Sedana Medical?

We're in the midst of an intensive build-up and expansion phase, with many parallel activities. I'm not sure what I can say I'm proud of as yet, but I derive a great deal of job satisfaction working with the team in what we're on our way to do – establishing a new therapy for intensive care patients that I believe benefits them and improves intensive care.

AnaConDa and IsoConDa are now fully developed, so what does your job as CMO entail today?

AnaConDa is approved in Europe and in a number of other countries. We still need to get European approval of IsoConDa, and that involves extensive work. We still need to get approval for AnaConDa and IsoConDa in the USA and a number of other countries, and my department and I are working on this in parallel with the European approval process. The European application process includes concluding the major registration study in Germany.

The next step is to carry out a major, multi-center study with IsoConDa with children in intensive care so that the therapy can also be approved for children. Alongside our work in gaining approval for the therapy, my ambition is to make our colleagues in intensive care units aware of the therapy. Because the therapy includes both a drug and a medical device, we're developing and simplifying handling and are busy creating a web-based global training platform. The development work is done in collaboration with physicians, nurses and experts in Human Factors.

How important is it that AnaConDa is used together with IsoConDa?

There's no simple answer. Currently, neither isoflurane nor sevoflurane include the indication intensive care sedation and physicians around the world have different preferences. When IsoConDa is approved, it will be the only approved product available and as such should then be the one used clinically. We will also be able to market IsoConDa.

But the anesthetic gases prescribed remain the attending physician's choice.

Why can't you use regular anesthesia machines?

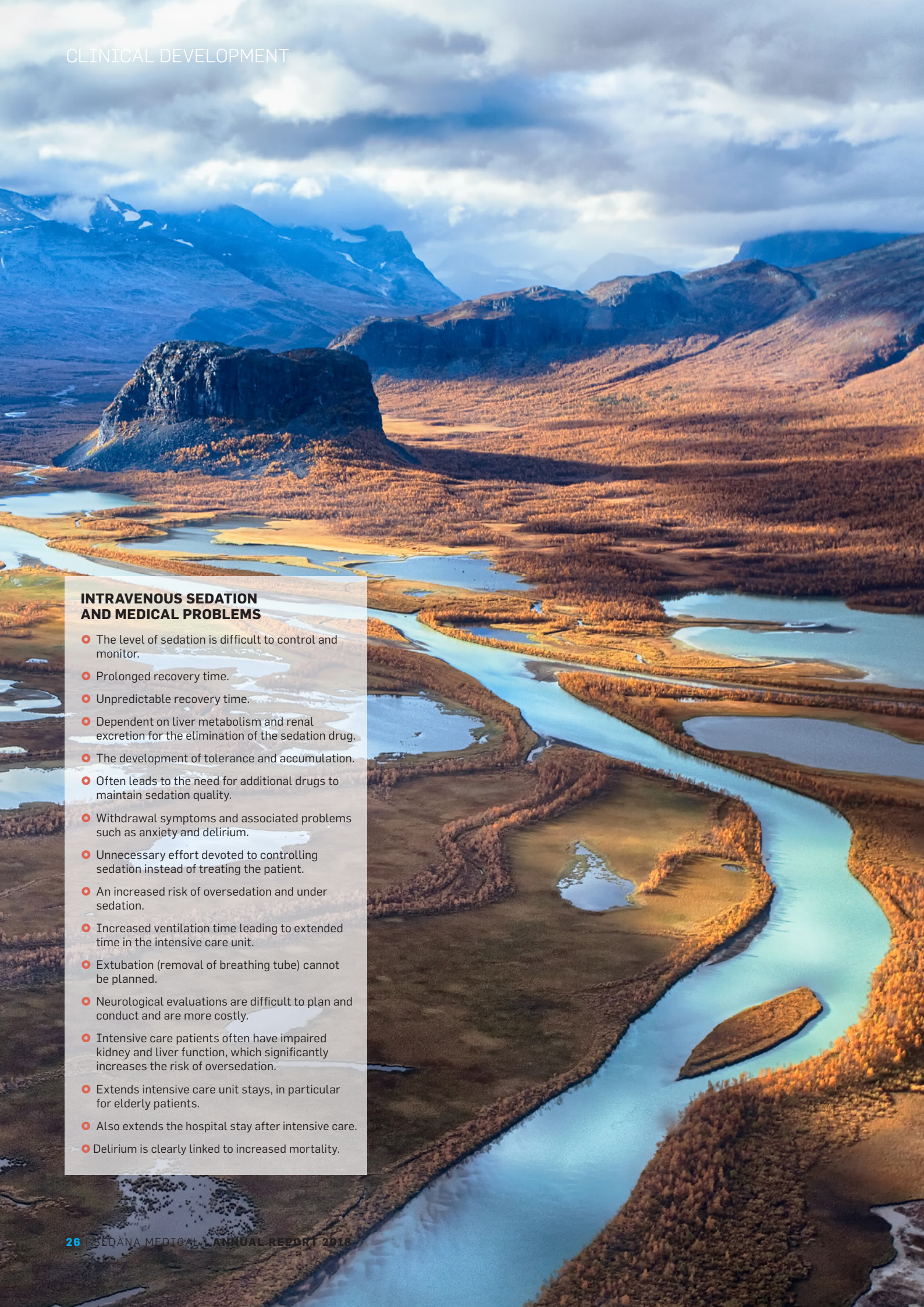
Anesthesia machines are not suitable for use in an intensive care environment. They are expensive, bulky and not as well suited to patients with respiratory diseases. Inhalation sedation underwent clinical studies back in the 80s and 90s and demonstrated many medical advantages, but the results from the studies could never be put into practice due to the lack of a simple, practical solution for administering inhalation anesthetics to intensive care patients.

If the advantages with inhalation sedation are so great, there just has to be competition, or what?

Conventional anesthesia machines are neither practical nor commercially suitable for intensive care. Other inhalation sedation solutions either fail to meet the standards of safety and efficiency required to achieve effective sedation in intensive care environments, or are too expensive.

What are the most important milestones moving forward?

In addition to concluding the IsoConDa study and submitting an application for EU approval, the most important milestones for me include getting started with the first patient in our children's intensive care study, finding out what is necessary to apply for a permit to register the therapy in the USA, getting those activities moving along and finally, launching our e-learning platform.



INTRAVENOUS SEDATION AND MEDICAL PROBLEMS

- The level of sedation is difficult to control and monitor.
- Prolonged recovery time.
- Unpredictable recovery time.
- Dependent on liver metabolism and renal excretion for the elimination of the sedation drug.
- The development of tolerance and accumulation.
- Often leads to the need for additional drugs to maintain sedation quality.
- Withdrawal symptoms and associated problems such as anxiety and delirium.
- Unnecessary effort devoted to controlling sedation instead of treating the patient.
- An increased risk of oversedation and under sedation.
- Increased ventilation time leading to extended time in the intensive care unit.
- Extubation (removal of breathing tube) cannot be planned.
- Neurological evaluations are difficult to plan and conduct and are more costly.
- Intensive care patients often have impaired kidney and liver function, which significantly increases the risk of oversedation.
- Extends intensive care unit stays, in particular for elderly patients.
- Also extends the hospital stay after intensive care.
- Delirium is clearly linked to increased mortality.

THE PURPOSE IS TO CONFIRM EFFICACY AND SAFETY

Sedana Medical's vision is to develop inhalation sedation into the standard global sedation method for mechanically ventilated patients in intensive care. The first step will be to register the drug candidate IsoConDa (isoflurane) and thus also inhalation sedation in Europe.

In 2017, Sedana Medical initiated a clinical phase III study as the basis for registration aimed at getting IsoConDa (isoflurane) approved for inhalation sedation in intensive care in Europe.

IsoConDa is Sedana Medical's brand name for the generic pharmaceutical substance isoflurane, which is currently only approved for use in general anesthesia.

The study's first patient was recruited in the middle of 2017. The study is a so-called random, controlled and open study. The purpose is to confirm efficacy and safety during sedation with isoflurane of patients mechanically ventilated with the aid of AnaConDa in comparison with propofol administered intravenously.

The study is currently underway in around 20 centers in Germany and completion is anticipated in the beginning of 2020. In parallel with the study, other documentation necessary for an application for marketing authorization, a pre-clinical evaluation and a pharmaceutical/technical summary are being compiled. The application will also include a plan for evaluating the use of IsoConDa on children in a so-called pediatric investigation plan (PIP).

Once the submitted registration documentation is complete, i.e. also including children, approval will mean that Sedana Medical will enjoy 10 years' marketing exclusivity in Europe for the use of isoflurane for sedation within intensive care. During this period, no competitor will be able to sell or market isoflurane for this purpose without their having undergone the same procedure as Sedana Medical.

> **Market approval** would give us 10 years' market exclusivity in Europe."

Because Sedana Medical's sales of AnaConDa have been seriously hampered by the fact that IsoConDa is as yet not approved, an important part of the company's growth strategy is to conclude the registration study currently in progress and which is expected to result in marketing authorization during 2021. Once authorization is obtained, it will be possible to actively market IsoConDa and AnaConDa for their proper fields of application, which is expected to have a significant effect on sales. Moreover, Sedana Medical expects general acceptance of the therapy to increase markedly following authorization.

In parallel with the study, efforts are continuing to increase the use of AnaConDa technology and establish the company in several European countries. In 2018, Sedana Medical set up its own sales organizations in Norway, Denmark and the United Kingdom. In order to quickly penetrate the market, the plan is to establish representation, networks and reference clinics in multiple European countries once authorization for IsoConDa is granted.

300

THE STUDY COMPRISES
a total of up to 300 mechanically ventilated intensive care patients in need of sedation.

The study

The study is a non-inferiority trial, which means that its primary objective is to demonstrate that IsoConDa administered using AnaConDa is not inferior to propofol in maintaining an adequate level of sedation. The study will include 300 mechanically ventilated intensive care patients in need of sedation. The patients are split into two groups of equal size where one is treated with propofol intravenously, and the other with IsoConDa administered by AnaConDa.

1 **Demonstrate that Isoflurane administered with AnaConDa is not inferior to propofol.** This will be determined by analyzing how large a share of the time during which an adequate level of sedation was maintained using isoflurane in compared to propofol.

Objective

Primary objective:

Demonstrate that Isoflurane administered with AnaConDa is not inferior to propofol. This will be determined by analyzing how large a share of the time during which an adequate level of sedation was maintained using isoflurane in comparison with propofol.

Secondary objective:

In the case of patients sedated with isoflurane in comparison with propofol, the study will evaluate:

The safety profile with regard to side effects in the form of changes in the biochemical laboratory values, vital parameters and organ functions.

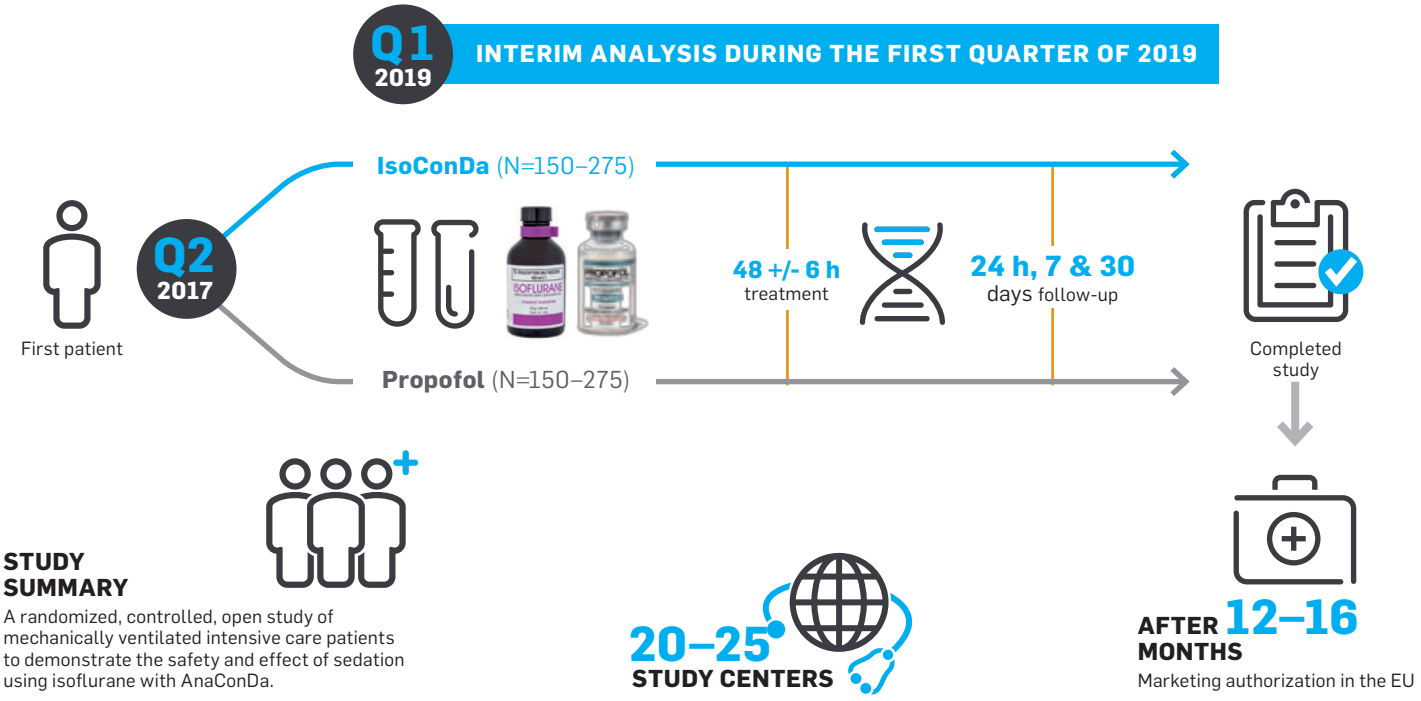
- Time taken to wake up, daily wakening
- Need for opiate analgesics (pain relief) in relation to the estimated pain level
- Ability to sustain spontaneous breathing during sedation
- Time in mechanical ventilation and the number of days in the intensive care unit during the first 30 days after conclusion of the study.
- Time from completed sedation to extubation

Research objectives:

Differences in sequential organ failure assessments; mortality in addition to the specific objectives for IsoConDa and AnaConDa.

European registration study

Phase 3 non-inferiority study: IsoConDa compared with propofol



Registration

In the USA

Registration work for both the drug and the medical device has begun in the USA, and during 2018 Sedana Medical was informed that the first meeting with the Food and Drug Administration (FDA) will take place at the end of March 2019. The meeting will clarify the requirements we must fulfill in order to gain approval for both products in the USA. Only after the meeting, when we receive the final protocol from the FDA, will we be able to set forth a more detailed timetable as to when the therapy could gain approval in the USA.

The market potential for inhalation sedation is greater in the USA than in Europe, primarily due to significantly higher price levels for sedation drugs in the USA. Nor is there any similar therapy currently available on the American market. The current method for sedation within intensive care in the USA is very reminiscent of that in Europe, where intravenous sedation using propofol, dexmedetomidine and benzodiazepines are the prevailing treatments.

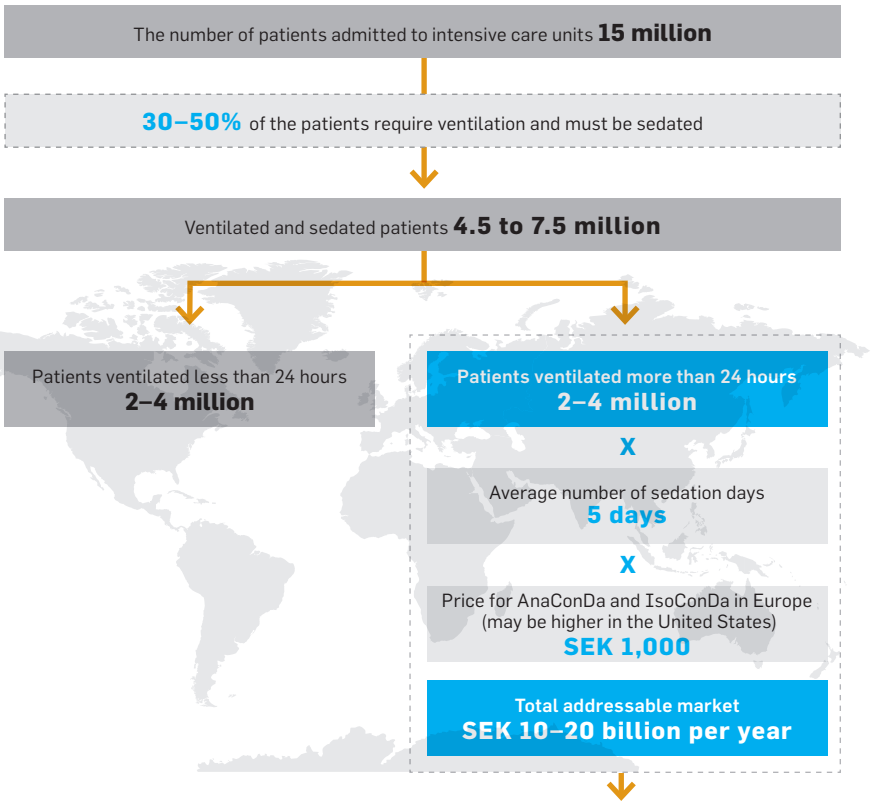
The rest of the world

Sedana Medical is also working to develop the therapy in Asia, e.g. in Japan, South Korea and China. In November 2018, Sedana Medical received marketing authorization for AnaConDa in Japan from the Japanese Ministry of Health, Labour and Welfare. Approval means that AnaConDa may be marketed, sold and used for the administration of volatile anesthetic drugs for mechanically ventilated patients in Japan. Sedana Medical is now working to enable the company's Japanese distributor to launch AnaConDa in Japan during 2019.

Sedana Medical calculates that mechanically ventilated patients in Japanese intensive care clinics add up to just over 1 million ventilation treatment days per annum. The company's strategy is to cultivate the Japanese market in the same way as that of Europe by primarily building up the use of AnaConDa in order to initiate a parallel evaluation of the registration work for IsoConDa.

Sedana Medical's market potential

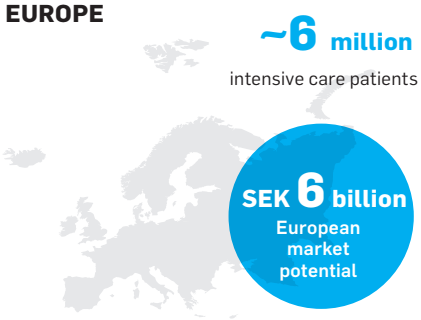
*Distribution of total market potential for AnaConDa/IsoConDa**



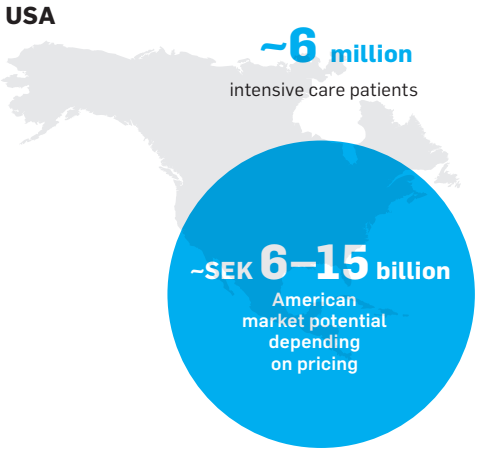
*Market size based on the company's estimates.

Sedana will initially focus on:

EUROPE



USA



IT'S GREAT TO WORK WITH PROFESSIONALS

Professor Thomas Volk is the principal investigator for the IsoConDa study, the world's biggest inhalation sedation study.

"I first came in contact with Sedana Medical's previous CEO, Ola Magnusson, when the company was founded, and I helped initiate the current study. It's the world's biggest inhalation sedation study and I'm convinced that it's essential," says Professor Thomas Volk.

When did you make contact with Sedana Medical for the first time?

I first encountered the therapy around 15 years ago, and during 2009 I was working in Homburg together with Dr. Andreas Meiser from Ruhr University Bochum. He's one of the world's three foremost authorities on inhalation sedation, and implementing the therapy in our intensive care unit has been his passion.

Did you see a rapid adoption rate for the therapy?

No, mainly because people were reluctant to change for the simple reason that people in general always resist change. To make the technology as good as it could be we went through every control step and consulted experts to help us e.g. minimize particles from the device that could jeopardize personnel health. It took us almost two years. Doctors and nurses saw that the procedure has advantages and is so easy to set up in intensive care that it soon became a matter of routine.

Germany is Sedana Medical's biggest market; just why exactly has Sedana Medical had such success in Germany?

In 2010, new guidelines for sedation were published in Germany describing the advantages of using inhalation sedation for certain patient groups. This helped to raise interest in the treatment. My colleague Dr. Andreas Meiser was a member of the group that wrote the guidelines.

What can you tell us about the current IsoConDa study?

I first came in contact with Sedana Medical's previous CEO, Ola Magnusson, when the company was founded, and I helped initiate the current study. It's the world's biggest inhalation sedation study and I'm convinced that it's essential. All of the procedures with the regulatory authorities in this type of study are very difficult to negotiate. It's been great working with the professional staff members at Sedana Medical in this process. The problems that arose with the study during the year were solved very elegantly thanks to everyone involved, and at the end of the day intensive care as a whole will benefit from what is been achieved. Hopefully, we can conclude the study soon.

Why is the success of this study so important?

We have a fantastic indication that the therapy will lead to better patient outcomes. We cannot point to better patient outcomes yet, but the results from the IsoConDa study will help us do so.

Do you think the therapy will be adopted quickly once the study is concluded?

That's not something I want to speculate about. Over the years we've seen many, major trials that failed to show significant benefits for intensive care patients. The AnaConDa system has the potential to be more successful.

PRODUCT SPECIALISTS WITH KNOW-HOW AND EXPERIENCE

It takes a long while to establish a new treatment therapy in healthcare, and it requires public opinion influencers in the field to back the therapy. If a treatment does not gain the support of such people and expert healthcare bodies, it will be very difficult to succeed. Accordingly, Sedana Medical has long focused on establishing contacts with precisely these groups in order to build and develop the therapy together.

This has been done with the aid of clinical studies, education, scientific congresses, the exchange of information and experience, and new guidelines. Because such activities must be managed by Sedana Medical, there is a clear advantage in conducting sales under its own auspices.

Sedana Medical's sales have hitherto taken place through conventional direct sales and dealers. The company works with product specialists that train clinicians in how the products work and how treatment should be carried out. The product specialists recruited by Sedana Medical consists mainly of nurses with a background in intensive care, which means they possess the knowledge and experience necessary for training customers.

Direct selling

Direct selling is Sedana Medical's preferred sales channel, and accounts for more than 90 percent of the company's total sales. In Germany, France, the Nordics, Spain and the United Kingdom, direct selling takes place primarily through in-house product specialists who also train customers in how to begin treatment safely. Direct selling is associated with higher costs than sales through distributors, and is usually established in major markets once good sales have been achieved through dealers. The benefits associated with direct selling include Sedana Medical's ability to control the sales process to a greater degree while also enjoying higher margins. The plan is for the in-house sales organization to cover the most important European markets in connection with the registration of IsoConDa in Europe.

Sales through dealers

Sedana Medical has engaged dealers as a low risk means of quickly establishing inhalation sedation for intensive care in countries where it does not conduct direct sales. Sedana Medical currently has distributor agreements in places such as Australia, the Middle East, Canada, Croatia, Slovenia, Japan and South Korea. In the short term, the company has no intention of setting up sales offices in these markets, but still feels the long-term potential to be of interest.

Customer base

Sedana Medical's customer base consists primarily of intensive care units in medium, large and university hospitals. The product is bought for the clinics via hospital procurement departments and in many cases Sedana Medical receives requests to participate in procurements. Sedana Medical's biggest market is Germany which, together with other markets where it conducts direct selling, has functioned as a test market to study demand for the therapy. Despite the fact that Sedana Medical has only assisted customers in the test markets, it has noted an increase in demand for the therapy.

The company also reaches out to its customers by taking part in exhibitions such as ESCIM, ICICEM, DIVI, DAC, SFAR, and SLRS and through the presentation by leading researchers and clinicians of their findings at scientific congresses sponsored by the company and by providing assistance for therapy initialization at clinics. Sales differ between countries and regions but common for all markets is the ambition to create demand among doctors and nurses who, together with intensive care patients, are AnaConDa's end customers.

“This therapy helps us achieve two important objectives – sedation and organ protection – with one single drug.”

Professor Daniel Talmor, anesthesiologist and physician at Beth Israel Deaconess Medical Center.

"INHALATION SEDATION IS A POTENTIAL PARADIGM SHIFT IN INTENSIVE CARE"

Inhalation sedation is one of the biggest innovations in intensive care for many years. Professor Talmor is convinced that volatile anesthetics can improve outcomes for ventilated patients and he wants to play a part in introducing the therapy to the USA.

Professor Daniel Talmor, you are an anesthesiologist and physician at Beth Israel Deaconess Medical Center, part of Harvard University. You also chair the Department of Anesthesia, Critical Care, and Pain Medicine.

Yes, I have 20 years' experience of intensive care and extensive experience from the operating room.

When was your first contact with Sedana Medical?

About four years ago, I became interested in inhalation sedation as we had a project in which rats underwent such sedation. The idea was to provoke lung damage in the rats, but we were unable to get them to develop any injuries. The result surprised me, so when I began looking around the world for companies that had an inhalation device, I came across Sedana Medical.

What's so special about AnaConDa and Sedana Medical?

AnaConDa is a proven delivery device that can be used in intensive care, and it has already been used in the treatment of thousands of patients. In all, it adds up to hundreds of thousands of patient days. Right now, Sedana Medical does not have any real competition.

What's so special about the therapy?

Today, there are so very few alternatives for protecting the lungs of critically ill people. This therapy helps us achieve two important objectives – sedation and organ protection – with one single drug. Inhalation sedation is a potential paradigm shift in intensive care.

What obstacles do you foresee for the company moving forward?

Most clinicians are conservative and because the therapy represents a paradigm shift, there's work to be done to convince them; scientific evidence will be important in this process. I'm convinced that it should be investigated as an organ-protective therapy in intensive care. After that, implementation of the therapy will require suitable training and marketing. But we're not there yet; persuading people will require more evidence. And the fact that in the USA the clinicians concerned are for the most part pulmonologists and not anesthesiologists can be another issue. But it's doable.

THE COMPETITIVE SITUATION

Sedana Medical is counting on IsoConDa, together with its delivery system AnaConDa, being the first treatment approved for inhalation sedation within intensive care. Furthermore, the company considers it to be highly unlikely that any other volatile drug is undergoing registration.

There is currently one alternative delivery system for volatile drugs known as Mirus from the German company Technologie Institut Medizin GmbH, TIM. Mirus has no drug approval and is a relatively expensive system (the initial investment is around EUR 15,000–23,000). Mirus has been on the German market for five years without making any major inroads. Only limited data is available regarding the safety and efficacy of Mirus, and Sedana Medical considers it unlikely that TIM would register a volatile drug.

Intellectual property rights

Sedana Medical's freedom-to-operate analysis, which checks the risks of infringement upon the intellectual property rights of others, has not brought to light anything that prevents development of the company and commercialization of the therapy. It included a competition analysis of existing therapies and therapies under development.

Sedana Medical has an active strategy for intellectual property rights and seeks to maximize the protection of its products and technical innovations. To protect these rights, Sedana Medical uses a three-part strategy that includes patent protection, obstacles and registrations.

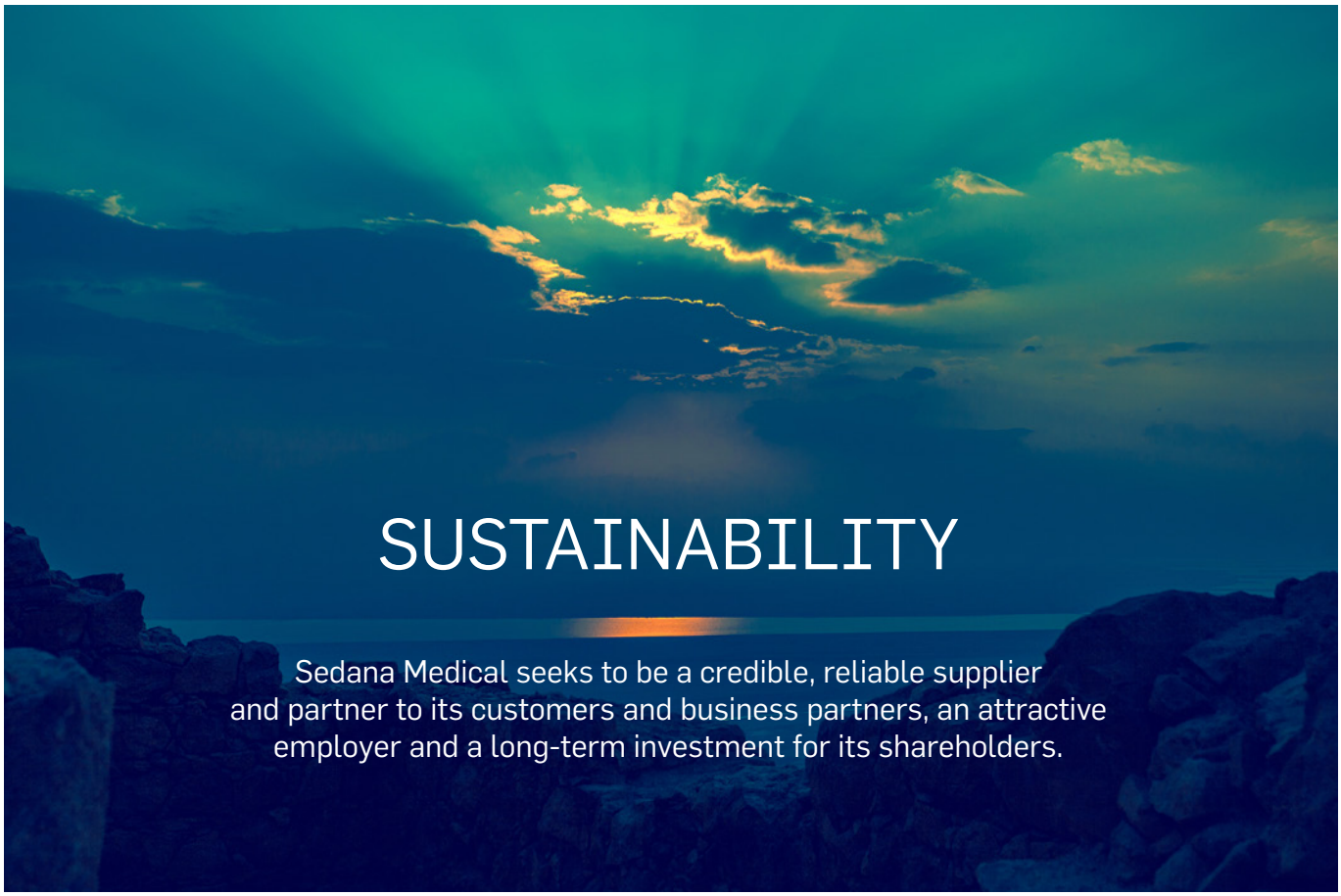
Patent protection Since the development of AnaConDa, Sedana Medical has protected its innovations through patents. Sedana Medical's patent portfolio currently includes five patent families and two patent applications. The basic patent for the outgoing AnaConDa model (100 ml) expired in 2018. Two new patent applications were submitted in 2016 for the newly developed AnaConDa-S (50 ml). One is in respect of the unit's design and the other is intended to prevent competitors from modifying the first generation AnaConDa (100 ml) to create a product with 50 ml dead space.

Obstacles As extra protection, Sedana Medical is developing solutions where the entire process from fluid in the bottle to patient delivery as gas can be protected. Furthermore, these protections make it easier and safer to connect the AnaConDa system while also making it difficult to connect generic drugs. The protections consist of unique connections and alternative packaging solutions.

Registrations Sedana Medical will register IsoConDa in Europe and thus gain a 10-year exclusivity period on the European market. The registration applies to IsoConDa administered by AnaConDa. Other combinations of volatile anesthetic gases and delivery methods for sedation in intensive care will continue to be off label. Other use of volatile anesthetics such as sevoflurane and desflurane for the indication of sedation will also continue to be off label.

In addition to these three strategies, Sedana Medical has extensive knowledge about inhalation sedation generated during the past 10 years and active, successful product development. The three strategies, together with the company's knowhow and product development, provide Sedana Medical with strong protections and a stable basis for planned marketing initiatives.

With regard to the American market, Sedana Medical is investigating the possibility of registering AnaConDa and IsoConDa as a combination product, which means that the only way to provide inhalation sedation for intensive care in the USA will be to use Sedana Medical's two products together.



SUSTAINABILITY

Sedana Medical seeks to be a credible, reliable supplier and partner to its customers and business partners, an attractive employer and a long-term investment for its shareholders.

Sedana Medical seeks to be a credible, reliable supplier and partner to its customers and business partners, an attractive employer and a long-term investment for its shareholders.

In the company's code of conduct, Sedana Medical's Board of Directors has laid down the ethical business practices that form the basis on which the operation must be conducted. The code is an important tool for the prevention and detection of any violation of the law, regulations or ethics. Business activities must always comply with local and global legislation, good practice and rules.

The code of conduct covers all employees, the board, suppliers, consultants and any temporary personnel. Sedana Medical's code of conduct also includes areas such as sustainability efforts, the work environment, health and safety, the environment, equal opportunities and purchasing.

In its R&D work, Sedana Medical complies with the Helsinki Declaration covering ethical principles governing how research and development involving humans must be conducted, and international standards such as good laboratory practices (GLP) and good clinical practices (GCP).

Operations must be run in an environmentally sustainable manner on the basis of the operation's conditions. Every person in the company must carry out his or her work with as little impact on health and the environment as possible and strive for continuous improvement. Goods and services must be delivered with an awareness of, and care for, the environment.

No form of inappropriate payment, direct or indirect, will be tolerated regardless of whether it concerns a direct bribe or other type of payment, gift, benefit, remuneration or other representation that could constitute a violation of the law or which could influence or be thought to influence judgment.

Quality management

Sedana Medical's business is quality certified according to ISO13485:2016.

Sedana Medical strives for openness and transparency in its business operations, and its sustainability management is under constant development.

SHARE INFORMATION

Sedana Medical's share was listed on Nasdaq First North Stockholm on June 21, 2017 and is included in both First North All share SEK and First North Health Care PI index.

Facts about the Sedana Medical share

Market	Nasdaq First North Stockholm
Number of shares*	19,156,591
Stock market value, SEK million*	1490
Ticker	SEDANA
ISIN	SE0009947534

*As of 12/31/2018

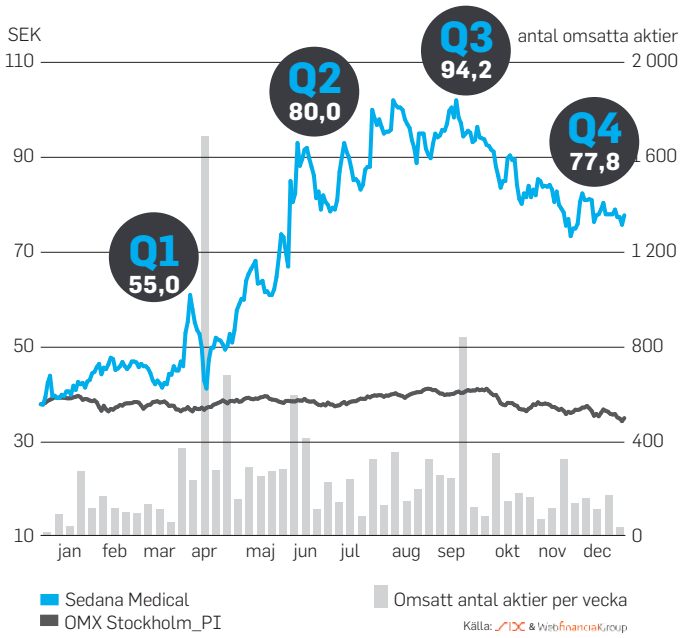
Nasdaq First North and Certified Adviser

First North is an alternative market for Nordic growth companies designed primarily for small and medium-sized enterprises. It does not have the same legal status as a regulated market and its regulatory framework is somewhat less extensive than those applicable in the exchange's bigger markets. Every company whose stock is traded on First North has a Certified Adviser who monitors the company's compliance with First North's regulations for the provision of information to the market and investors. Sedana Medical's appointed Certified Adviser is Erik Penser Bank, phone: +46 8 463 83 00, email: certifiedadviser@penser.se.

Share capital

The total number of shares outstanding as of December 31, 2018 amounted to 19,156,591. At year-end, share capital amounted to SEK 1,915,659. Each share entitles the holder to one vote, and every shareholder has the right to vote his or her full number of shares at the annual general meeting. All outstanding shares are fully paid. The company's share capital is reported in Swedish crowns and distributed across the company's outstanding shares at a quota value of SEK 0.10 per share.

Sedana Medical's share price trend and turnover



Share trading

The introductory price upon listing in 2017 was SEK 19.50. The opening price in 2018 was SEK 38 and the final price paid at year-end was SEK 77.80. During the year, a total of 12,574,121 million Sedana Medical shares were turned over at a value of SEK 886 billion, equivalent to a turnover rate of 66 percent. On average, 50,296 shares changed hands per trading day.

Share capital development over time

Date of adoption	Event	Change in shares	Total number of shares	Change in share capital (SEK)	Total share capital (SEK)	Quota value (SEK)
10/20/2004	New formation	1,000	1,000	100,000	100,000	100
10/31/2009	New share issue	430	1,430	43,000	143,000	100
5/5/2011	New share issue	500	1,930	50,000	193,000	100
9/14/2015	New share issue	240	2,170	24,000	240,000	100
4/5/2017	Bonus issue	6,510	8,680	651,000	868,000	100
4/5/2017	Split [1)]	8,671,320	8,680,000	0	868,000	0.1
6/20/2017	Conversion of shareholder loans	613,594	9,293,594	61,359	929,359	0.1
6/20/2017	Exercised convertible bonds	1,881,509	11,175,103	188,151	1,117,510	0.1
6/20/2017	New share issue at the IPO	5,128,205	16,303,308	512,821	1,630,331	0.1
7/10/2017	Overallotment option after IPO	769,230	17,072,538	76,923	1,707,254	0.1
2/5/2018	Conversion of options to shares, program 2014/2019	208,000	17,280,538	20,800	1,728,054	0.1
6/4/2018	New share issue	1,728,053	19,008,591	172,805	1,900,859	0.1
10/10/2018	Conversion of options to shares, program 2014/2019	148,000	19,156,591	14,800	1,915,659	0.1

1) Share split 1:1000.

Price trend

During the year, Sedana Medical stock climbed 105 percent from its introductory price, while the First North All Share index during the same period rose by 4.6 percent.

The highest price paid was SEK 109 noted on 8/8/2018, and the lowest price was SEK 37.2 noted on 1/2/2018.
At year-end 2018, Sedana Medical stock was listed at SEK 77.8, equivalent to a market capitalization of SEK 1490 million.

The 15 largest shareholders as of December 31, 2018

	Number of shares	Holding
Linc AB	1,901,901	9.93%
Sten Gibeck	1,605,744	8.38%
Magiola Consulting	1,355,867	7.08%
Anders Walldow directly and indirectly (Brohuvudet AB)	1,160,000	6.06%
Anades Ltd.	1,068,083	5.58%
State Street Bank & Trust	796,123	4.16%
Ron Farrell	731,062	3.82%
SEB	723,216	3.78%
Handelsbanken Microcap	592,990	3.10%
Eklund Konsulting AB	474,156	2.48%
BNP Paribas	457,085	2.39%
Eklund Konsulting AB	474,156	2.48%
Swedbank Robur Microcap	450,000	2.42%
Avanza pension	448,709	2.35%
Nordnet pensionsförsäkrings AB	404,090	2.34%
The 15 largest shareholders	12,702,492	66.31%
Other*	6,454,099	33.69%
Total	**19,156,591**	**100.00%**

*The CEO's holding is 230,000 shares.

Shareholder distribution by size

	Number of shareholders	Number of shares	%
1–500	1,195	169,533	0.88%
501–1,000	183	146,715	0.77%
1,001–5,000	183	442,923	2.31%
5,001–10,000	41	286,245	1.49%
10,001–15,000	15	183,228	0.96%
15,001–20,000	10	172,739	0.90%
20,001–	68	17,755,208	92.68%
Total	**1,695**	**19,156,591**	**100%**

Source: Euroclear Sweden

Incentive program

The annual general meeting of May 19, 2017 resolved to establish a warrant-based incentive program aimed at
key company personnel. In this context, a resolution was adopted on the issue of a total of 310,149 2017/2021 series warrants. all of which were subscribed to and allocated to the Company's subsidiary Sedana Medical Incentives AB for onward transfer to the participants
in the incentive program. A total of 310,149 warrants were transferred to the participants in the program. All participants are senior executives in the company. The warrants were transferred under market terms. The transfer price was calculated with the aid of the Black & Scholes model by an independent institute. Each warrant entitles the holder to subscribe to one share in the company at a subscription price equivalent to 130 percent of the issue price in the IPO, i.e. SEK 19.50.

The warrants may be exercised during the period May 15, 2020 through January 31, 2021. The warrants are also subject to customary conditions for conversion in connection with new issues etc.

If all of the warrants transferred to participants in the incentive program are exercised, the company's
share capital will increase by around SEK 31,015 through the issue of 310,149 shares, equivalent to a dilution of around 1.8 percent based on the number of shares in the company on the closing date.

Warrants program

The company has 171 outstanding 2014/2019 series warrants issued at the extraordinary general meeting on June 24, 2014. The warrants entitle holders to subscribe to shares in Sedana Medical during the period from the warrant registration date through December 31, 2019. The warrants are subject to customary conversion conditions should the company make changes to the share capital and/or the number of shares through e.g. a new share issue, bonus issue, consolidation or a share split. Each warrant entitles the holder to subscribe to 4,000 shares. In all, the total number of outstanding warrants entitle subscriptions to 684,000 shares at a subscription price equivalent to SEK 2.5 per share.

All of the 2014/2019 series warrants have been subscribed to by existing shareholders, related parties and senior executives in the company. If all of the remaining 2014/2019 series warrants are subscribed to, the company's share capital will rise by SEK 68,400 through the issue of 684,000 shares in the company equivalent to a dilution of 3.6 percent based on the number of shares in the company on the closing date.

ADMINISTRATION REPORT

The business in brief

Sedana Medical is a Swedish medical devices group that is also on its way to becoming a pharmaceutical company. The Group's operations comprise the development, manufacture and sales of medical devices and the development of products and drugs based on, or which have synergies with, AnaConDa technology. The technology enables the simple, safe conversion of a liquid to a gas (evaporation) and the reuse (reflection) of volatile anesthetics for the sedation of intensive care patients. The Group's product portfolio currently includes AnaConDa with accessories and in the near future IsoConDa, the Group's drug candidate based on the well-known substance Isoflurane.

Volatile anesthetics have long been used to anesthetize patients in connection with surgery. Complex, capital-intensive anesthesia machines that require specially trained personnel are used for this purpose. Traditional anesthesia machines lack several vital characteristics, which prevents their routine use in intensive care units. The Group's AnaConDa product, which in very simple terms can be regarded as an anesthesia machine in miniature, is a solution that makes it practically and financially possible to use volatile anesthetics to sedate mechanically ventilated intensive care patients. The market for the sedation of mechanically ventilated intensive care patients today consists of established drugs that are administered intravenously. Sedation through the inhalation of volatile anesthetics has shown itself in many ways to be a safer, more effective solution for sedating intensive care patients than current intravenous sedation.

Sedana Medical's vision is to develop inhalation sedation using IsoConDa and AnaConDa into the standard global sedation method for mechanically ventilated patients in intensive care. To achieve this vision, the Group has been conducting a clinical phase III registration study since the fall of 2016 aimed at gaining approval for the drug IsoConDa and inhalation sedation therapy using AnaConDa. If all goes well, Sedana Medical anticipates obtaining European market approval in the second half of 2021.

Sedana Medical runs its own sales operations from a number of countries in Europe via subsidiaries and affiliates to the parent company Sedana Medical AB (publ), corporate ID number 556670–2519. The operation in Germany consists of sales, storage and distribution. This is run by a branch of the parent company. In Spain, sales operations are run by a branch of the parent company. Germany is by far the Group's biggest market with over 85 percent of total sales. In addition to Germany, direct sales also take place in Spain and France through the wholly-owned subsidiary Sedana Medical SARL, and in the Nordics and the United Kingdom through the parent company. In several other countries around the world, sales take place through collaborations with distributors. The Company conducts R&D in Ireland through its wholly owned subsidiary, Sedana Medical Ltd. AnaConDa products are manufactured by subcontractors, but controlled via the Irish subsidiary. The parent company's head office and domicile is in Danderyd, Sweden. In June 2017, the company's stock was listed (ticker: SEDANA) on the Nasdaq First North exchange.

Significant events January–December 2018

FIRST QUARTER

- The number of shares increased by 208,000 due to exercises of the options program 2014/2019.
- Peter Sackey took up his position as Chief Medical Officer on January 8, 2018.
- Sedana Medical AB (publ) opened its own sales operations in Norway and Denmark.

SECOND QUARTER

- Sedana Medical AB (publ) announced that the schedule for patient recruitment to the current phase III IsoConDa study will probably be extended.
- Sedana Medical AB (publ) announced a record sales increase during the first quarter of 2018.
- Sedana Medical AB (publ) carried out a new share issue in the amount of SEK 112 million aimed at institutional investors.
- Sedana Medical AB (publ) announced its recruitment of Gunilla Mickelsson as marketing director.

THIRD QUARTER

- On July 26, Sedana Medical AB (publ) announced that it had received approval from the central ethics committee for the phase 3 study essential for registering IsoConDa in Germany, and to revert to its original study protocol following certain clarifications. This means the study can now be resumed in full following the limitations at the beginning of April this year.
- Sedana Medical AB (publ) announced the first direct sales of AnaConDa in the United Kingdom.

FOURTH QUARTER

- Sedana Medical AB (publ) obtained approval for AnaConDa in Japan.
- At the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Europe 2018 congress in Barcelona, Sedana Medical AB (publ) presented a health economics analysis showing the clinical and financial advantages of using inhalation sedation with Isoflurane via AnaConDa compared to conventional intravenous sedation using propofol or midazolam.

Anticipated future developments

In the coming years, the Group will apply its strategy to realize its business idea and vision and achieve its financial objectives.

BUSINESS CONCEPT

To provide a solution for many of the problems that today's intravenous sedation gives rise to. Inhalation sedation with the AnaConDa system, which administers the volatile anesthetic IsoConDa via the respiratory tract, enables efficient, safe, simple, controllable and cost-effective sedation for mechanically ventilated patients in intensive care.

VISION

To develop inhalation sedation with AnaConDa and IsoConDa into the standard method for the sedation of mechanically ventilated patients in intensive care.

FINANCIAL TARGETS

The company's objective leading up to the approval and registration of IsoConDa, is to increase average annual sales by more than 20 percent while maintaining operating profits before depreciations and impairment charges (EBITDA) without becoming materially negative while building up a major sales and marketing organization. Sedana Medical's ambition is to achieve sales in excess of SEK 500 million (excluding the USA) and an EBITDA margin of 40 percent three years after registration of IsoConDa.

STRATEGY

The company has created, and abides by, a strategy that can be summarized by the following three points:

1. Registration of IsoConDa and inhalation sedation in Europe
2. Initiate the registration process for AnaConDa and IsoConDa in the USA.
3. In close collaboration with the market, prepare for an effective, successful launch of the products and the therapy following their registration first in the EU and later in the USA.

Risks

Sedana Medical's activities are affected by many factors that the company is able to control in some respects but not at all in others. These aspects can also be expressed as various risks. The risks can have a lesser or greater effect on the company's earnings and position depending on if and how they apply. Some of the risk factors considered to be of greatest significance for the company's future development are described below.

INDUSTRY AND OPERATIONS-RELATED RISKS

Risks related to the regulatory environment for medical devices and drugs

Sedana Medical's AnaConDa products and the forthcoming drug IsoConDa are subject to extensive regulation worldwide and are monitored by various industry-specific supervisory authorities. In addition to such industry-specific regulation, Sedana Medical is also subject to a number of other requirements and restrictions under the provisions of environmental, health and industrial safety legislation. There may be more such requirements moving forward. The cost of compliance with applicable legislation, requirements and guidelines can be great. Furthermore, the regulatory environment in general has become more stringent and extensive over time. Should these regulations not be followed, it can lead to sanctions that could significantly increase Sedana Medical's costs, entail delays in the development and the commercialization of the company's product candidates and substantially harm the ability to generate planned revenues and achieve profitability. If these risks become reality, they could have a significant adverse effect on the company's operations and financial position.

Risks related to the product classification system or market access process for medical devices and drugs

Before Sedana Medical's AnaConDa products may be marketed in the area of inhalation sedation treatment in intensive care in any new national or regional market, whether in combination with IsoConDa or not, the company must obtain marketing authorization or similar permits from the relevant authorities in the countries where the company intends to market and sell its products. Changes in the process and requirements for market access can adversely affect Sedana Medical's ability to generate desired revenues. In order for class II and III medical devices to be marketed in the EU, a so-called notified body must first issue a certificate confirming that the relevant regulatory requirements have been met. The company's certificate for its medical devices is valid until 2020. Because decisions taken by notified bodies are valid for a limited time, certificates must be renewed. This renewal process can be time-consuming, especially when the original application is extended to include new treatment areas or otherwise undergoes significant changes. All of the risks described above could have a significantly adverse effect on the company's operations, financial position and earnings.

Risks related to the implementation and outcomes of clinical studies

During the fourth quarter of 2016, Sedana Medical initiated clinical studies as the basis for registration in respect of its

drug candidate IsoConDa (Isoflurane) for use within the area of inhalation sedation treatment in intensive care. Completion of the study is crucial in order for the company to market its AnaConDa and AnaConDa-S products together with IsoConDa as a therapy for inhalation sedation in intensive care in the markets the company intends to focus on. The company is thus dependent on obtaining positive outcomes from the clinical studies in progress in order to achieve its long-term operational goals. The execution of clinical trials is associated with a number of risks. Among them are always the risks of delays and that the cost of studies will be higher than estimated. Delays can occur due to problems in finding venues for studies; in gaining the necessary authority approvals for the performance of studies, with recruiting patients; with concluding satisfactory agreements with e.g. contract research companies, suppliers, and study locations etc.

Not only can delays lead to increased costs, but also to late product launches which may result in the company's failure to generate revenues as planned. Increased costs can also occur due to expenditures per patient being higher than estimated or a lack of quality in the execution of the study in the hospitals where it is performed etc. Clinical studies may present negative or inadequate results in the treatment area Sedana Medical's products are aimed at. If the desired results are not achieved, it may mean the necessary market approvals fail to be issued, which can in turn jeopardize the company's ability to market and sell its products and product candidates. If the above risks become reality, they can have significant adverse effects on the company's ability to generate revenues and on its operations, financial position and earnings.

Risks related to third-party agreements in respect of e.g. the performance of clinical studies and manufacturing

Sedana Medical engages external companies such as contract research and development companies to perform clinical studies and to manufacture its products. The operations of such companies are subject to extensive requirements regarding e.g. reporting, safety and the environment. There is a risk that these companies do not comply with applicable legislation, regulation and the relevant ethical standards such as good manufacturing practices (GMP) and good clinical practices (GCP). There is also a risk of deficient or missed deliveries of products or services from external companies engaged today and in the future. This can affect the development and sales of Sedana Medical's products negatively by causing delays and increasing costs. The company is not dependent on any one contract research or manufacturing company, but changing suppliers can be both expensive and time-consuming. The occurrence of the risks described above could have an adverse effect on Sedana Medical's operations, financial position and earnings.

Risks related to unsuccessful market acceptance from healthcare providers, patients and healthcare payers including the ability to benefit from compensation systems

Even if a product meets the requirements for market access by e.g. obtaining marketing authorization, there is a risk that the desired level of market acceptance will not be achieved from doctors, hospitals, patients, healthcare payers and the industry in general, which could prevent Sedana Medical from generating and achieving desired revenues and could have a significant adverse effect on the company's operations, financial position and earnings.

Risks related to competition

Sedana Medical's inhalation sedation products for intensive care patients are primarily exposed to competition from sedation drugs for intravenous treatment. Intravenous sedation is a well-established therapy method and the standard treatment for the sedation of intensive care patients today. Even though Sedana Medical believes in its products' ability to take market share from companies that sell drugs for intravenous sedation, there is always a risk that the company will not achieve the desired market acceptance. And even if Sedana Medical were to succeed in taking market share from conventional methods with sedation drugs for intravenous treatment, there is a risk of exposure to competition within the indication inhalation sedation. The risks related to competition could have a significantly adverse effect on the company's operations, financial position and earnings.

Risks related to macro-economic factors including pricing and demand for medical products

Because Sedana Medical intends to market and sell its products in several parts of the world, the company can be affected by general demand and the pricing of products for sedating intensive care patients in the relevant markets. Sedana Medical cannot foresee developments in financial markets, the economic and political climates or macro-economic events such as a recession or weak growth, which may lead to stresses in the market for medical devices and drugs, leading to increasing pressure on hospitals, authorities and other healthcare payers to cut back on costs, potentially reducing the willingness to pay for such products in general, including those of Sedana Medical. If the risks described above become reality, they could have a significant adverse effect on the company's operations, financial position and earnings.

Dependence on sales and the development of a limited number of products

Today, Sedana Medical focuses mainly on sales of AnaConDa, and conducting clinical phase III studies of the IsoConDa drug candidate with the aim of obtaining marketing authorization for the product for use together with the company's AnaConDa medical devices. The company's growth target is based entirely on one

technology and one specific field of therapy, namely inhalation sedation in intensive care. Sedana Medical's operations, financial position and earnings would suffer significant adverse effects from any setback in the clinical phase III study.

Risks related to key individuals and qualified personnel

Sedana Medical is dependent on its employees, especially senior executives and other key staff. The company is dependent on its ability to recruit highly qualified personnel for the continued development of the operation. If Sedana Medical were to lose any of its key personnel or fail to recruit qualified personnel it could have a negative effect on the company's operations, financial position and earnings.

Risks related to the company's protection of its intellectual property rights

Patents and other intellectual property rights form a central asset in Sedana Medical's operation and thus any future successes are largely dependent on the company's abilities to maintain existing intellectual property rights such as brands and patents and to obtain protection for submitted and future patent applications. The company's patent for the old version of the AnaConDa product will run out shortly, and this will enable competitors to manufacture and sell competing products. Sedana Medical has applied for a patent for the new, improved product known as AnaConDa-S, which is expected to replace the old version shortly. If the company's patents and other intellectual property rights were to be lost or limited, or if the company otherwise cannot maintain the necessary patent protection, it could have a materially negative effect on the company's operations, financial position and earnings.

Risks related to fluctuating currency rates

The company reports its financial position and earnings in Swedish crowns. On the other hand, the majority of the company's operating costs and revenues are in euros, and in the future the company's operating revenues and costs are expected to comprise other currencies. As a result, Sedana Medical is exposed to exchange rate risks in relation to payment flows inside and outside Sweden and the eurozone, such as fluctuations where the exchange rate changes from the time an agreement is concluded until payment takes place under said agreement, which can lead to currency transaction losses or gains (so-called transaction exposure) that the company is unable to foresee. Currency transaction losses could entail significant adverse effects on the company's future operations, financial position and profits.

Risks related to current and additional financing

The amount of resources required to implement Sedana Medical's operational plan including the development and commercialization of medical devices and drugs depends on a number of factors that are unknown at present. There is a risk that Sedana Medical will not achieve sufficient revenues in time to be able to finance its operations and development. If the company cannot obtain acceptable financing, it may limit the company's ability to maintain its position in the market or make competitive offers. Sedana Medical may also be forced to seek additional financing in order to continue operations. Such financing can be sought through external investors or existing shareholders and take place through public or private financing initiatives. There is a risk that new capital cannot be obtained when needed or on acceptable terms or that the capital obtained is not sufficient to finance the operation according to established operational planning and objectives. If the risks associated with problems in obtaining sufficient revenues or sufficient financing to maintain the company's operations become reality, it could have a significant adverse effect on operations, financial position and earnings.

Risks related to exposure to tax demands and changes in tax regulations

In Sedana Medical's opinion, the company complies with applicable tax legislation. However, from time to time various alternative legislation may be proposed that will have a negative impact on the company's tax situation. Furthermore, tax regulations are complex and subject to different interpretations. There are no guarantees that Sedana Medical's tax situation will not be challenged by tax authorities or that the company will be successful should such an event occur. A decision by the tax authority could change Sedana Medical's earlier tax situation, which could have a negative impact on the company's operations, financial position and earnings.

Risks related to accumulated tax losses

Because the operation has generated significant losses, Sedana Medical has major accumulated tax losses. Changes in ownership that lead to an individual's gaining a controlling influence over the company could lead to limitations in the ability to make use of such losses in the future. The ability to make use of losses in the future may also be negatively affected by changes in applicable legislation. Such limitations and changes could have a negative effect on Sedana Medical's operations and financial position.

Multi-year financial overview

The Group's figures in summary

SEK thousand	2018	2017	2016	2015
Net Sales	57,896.2	40,427.7	32,154.6	28,113.5
Gross Profit	42,896.5	29,661.7	21,346.4	17,849.2
Earnings before interest, taxes, depreciation and amortization (EBITDA)	-4,232.3	-736.2	994.3	-1,174.2
Earnings Before Interest and Taxes (EBIT)	-8,238.2	-3,487.8	617.8	-1,386.7
Net income	-6,869.1	-3,875.7	1,285.6	-1,205.4
Gross Margin (%)	74.1%	73.4%	66.4%	63.5%
EBITDA %	-7.3%	-1.8%	3.1%	-4.2%
EBIT %	-14.2%	-8.6%	1.9%	-4.9%
Net income % of net sales	-11.9%	-9.6%	4.0%	-4.3%
Total assets	231,549.8	131,376.3	23,624.4	12,401.3
Equity ratio	94.1%	88.6%	5.3%	3.6%
Quick ratio	1,219.6%	640.4%	80.2%	131.8%
Average number of employees	26.2	16.5	15.7	11.0

The parent company's figures in summary

SEK thousand	2018	2017	2016	2015	2014
Net Sales	55,855.7	43,129.3	31,494.9	27,940.0	21,261.3
Gross Profit	21,126.5	16,669.2	13,339.2	12,105.1	11,708.0
Earnings before interest, taxes, depreciation and amortization (EBITDA)	-4,888.3	-4,263.3	1,345.5	6,088.5	164.7
Earnings Before Interest and Taxes (EBIT)	-6,431.4	-5,438.9	1,277.2	5,957.7	-830.5
Net income	-3,755.2	-4,626.7	1,659.1	6,179.5	-1,508.3
Gross Margin (%)	37.8%	38.6%	42.4%	43.3%	55.1%
EBITDA %	-8.8%	-9.9%	4.3%	21.8%	0.8%
EBIT %	-11.5%	-12.6%	4.1%	21.3%	-3.9%
Net income % of net sales	-6.7%	-10.7%	5.3%	22.1%	-7.1%
Total assets	257,059.7	143,883.5	38,328.8	31,230.9	18,734.4
Equity ratio	89.0%	86.1%	24.3%	57.6%	42.1%
Quick ratio	630.6%	489.4%	59.6%	251.6%	81.2%
Average number of employees	17.0	8.7	7.4	7.0	5.0

Financial overview

JANUARY–DECEMBER 2018

REVENUES

The Group's operating income for the full year 2018 amounted to SEK 59,371 thousand, which corresponds to an increase of SEK 16,080 thousand, of which net sales constituted an increase of SEK 17,468 thousand, or 43 percent. The Group's sales are exclusively in EUR, and the equivalent sales increase adjusted for currency fluctuations was 35 percent. Furthermore, the revenues include other operating revenues of SEK 1,474 thousand (1,572). Other operating revenues in 2018 comprised mainly positive exchange rate differences. The accumulated revenues for quarters 1–3 in 2017 include the capitalization of development costs in the amount of SEK 1,291 thousand. The same item can be found in other operating expenses for the corresponding period and shows capitalization of development expenses according to the gross accounting policy the Group applied up until the second quarter, 2017. During the third quarter of 2017, the Group made a departure from this accounting policy under the so-called K3 regulations.

GOODS FOR SALE

The cost of goods for sale amounted to SEK 15,000 thousand (10,776), equivalent to an increase of 39 percent compared to the full year 2017. The increase in the cost of goods for sale depends mainly on increased sales, but also the product mix.

OTHER EXTERNAL COSTS

Other external costs for the full year 2018 amounted to SEK 21,651 thousand (16,825), i.e. an increase of 29 percent compared to 2017, which is mainly due to increased selling and marketing costs. In general, Other external costs includes such things as consultancy fees, selling and marketing costs, the cost of accounting services, travel costs and patent costs.

PERSONNEL COSTS

Personnel costs in the Group amounted to SEK 25,760 thousand (16,195) for 2018, i.e. an increase of SEK 9,566 thousand or 59 percent in comparison with 2017. During 2018, the Group had an average of 26.2 employees, which was an increase of 9.7 employees compared with the same period in 2017. The increase in personnel costs is mainly due to a buildup of the sales and marketing organization before the registration and subsequent launch of IsoConDa.

DEPRECIATIONS AND IMPAIRMENT LOSSES

For the full year 2018, depreciations amounted to SEK 4,006 thousand (2,752), i.e. an increase of SEK 1,254 thousand compared with 2017. The increase reflects the full-year effect of the depreciation of the supplementary purchase price in respect of the rights for AnaConDa acquired from Teleflex in June 2017.

OPERATING LOSS

The Group's operating loss for the full year was SEK -8,238 thousand (-3,488) equivalent to a deterioration of SEK 4,750 thousand or 136 percent. The increased loss is explained mainly by the costs of building up the sales and marketing organization within the Group.

FINANCIAL ITEMS

Net financial income/expense amounted to SEK 1,719 thousand (-1,113) for the year. The net financial income is explained mainly by positive exchange rate changes.

TAXES

The Group reported at tax expense of SEK 349 thousand for 2018. Tax income of SEK 725 thousand was reported for the corresponding period during the previous year. The 2018 tax expense is due mainly to an adjustment of earlier allowed tax deductions in respect of R&D in the Group's subsidiary in Ireland. Tax income during the previous year was in respect of changes in deferred tax.

EARNINGS AFTER TAX

The Group reported earnings after tax of SEK -6,869 thousand (-3,876) for the year. The deterioration in earnings compared to the previous year is due mainly to lower operating earnings and higher tax.

EQUITY AND INDEBTEDNESS

As of December 31, 2018 equity in the Group amounted to SEK 217,811 thousand (116,403), equivalent to an increase of SEK 101,408 thousand. The increase is primarily due to the targeted new share issue carried out by the company at the beginning of June, 2018. At the end of the period, current liabilities in the Group amounted to SEK 13,738 thousand (14,973) comprising mainly accrued expenses of SEK 6,958 thousand (5,505) and trade accounts payable of SEK 4,430 thousand (7,873).

CASH AND CASH EQUIVALENTS AND CASH FLOW

Cash and cash equivalents at the end of the period amounted to SEK 159,351 thousand (85,322). Cash flow from operating activities before change in working capital amounted to SEK -2,761 thousand (-4,232). Cash flow from operating activities including the change in working capital amounted to SEK -5,779 thousand (496). The negative change in working capital compared with the same period for the previous year is primarily due to a reduction in operating liabilities. Cash flow from investments amounted to SEK -29,127 thousand (-25,882) comprising mainly intangible assets of which the major part concerns capitalized development costs and where expenses for the clinical study IsoConDa EU (SED001) constitute the main part. Cash flow from financing activities showed a net of SEK 108,774 thousand (102,340) due to the targeted new share issue carried out in June, 2018. Cash flow from financing activities includes issue expenses of SEK 4,439 thousand. Total cash flow for the full year amounted to SEK 73,869 thousand (76,953).

INVESTMENTS

Investments during the 2018 financial year amounted to SEK 29,127 thousand (25,882). Investments during 2018 are primarily in respect of:

- Capitalized expenses for development work, SEK 24,445 thousand
- Internal expenses for the preparation of patents, SEK 647 thousand
- The purchase of machinery and other technical facilities, SEK 3,675 thousand
- The purchase of fixtures, fittings and tools, SEK 320 thousand.

PARENT COMPANY

Sedana Medical AB (publ) Corporate ID number: 556670–2519, is the Group's parent company. The operation comprises clinical development, sales, administrative and company management functions. The parent company includes branch offices in Germany and Spain where operations consist of sales and product storage. The parent company's total revenues for the financial year amounted to SEK 66,479 thousand (44,542). The operating loss amounted to SEK -6,431 thousand (-5,439), equivalent to a decrease of SEK 993 thousand. Net financial income/expense in 2018 amounted to SEK 2,724 thousand (-536).

Earnings for the period amounted to SEK -3,755 thousand (-4,627). As of December 31, 2018 equity in the parent company, Sedana Medical AB (publ), amounted to SEK 228,710 thousand (123,947), equivalent to an increase of SEK 104,764 thousand compared to 2017. Share capital amounted to SEK 1,916 thousand (1,707), equivalent to an increase of SEK 208 thousand. Of the share capital increase, SEK 36 thousand is attributable to the conversion of options into shares in the 2014/2019 options program, while the rest is attributable to the targeted new share emission carried out in the beginning of June, 2018. Cash and cash equivalents amounted to SEK 158,805 thousand (83,283), an increase of SEK 75,523 thousand, due to the new share issue in the beginning of June, 2018.

Organization and Personnel

EMPLOYEES

At the end of 2018, Sedana Medical had 30 employees, of whom 19 were men, and 11 women. The corresponding figures at the end of 2017 were 25 employees, of whom 16 were men, and 9 women.

INCENTIVE PROGRAM

The annual general meeting (AGM) of May 19, 2017 resolved to establish a warrant-based incentive program aimed at key personnel in Sedana Medical. In this matter, the AGM resolved to issue a total of 310,149 series 2017/2021 warrants, all of which were subscribed to and allocated to the company's subsidiary Sedana Medical Incentive AB for onward transfer to the participants. A total of 310,149 warrants were transferred to the participants in the program. All of the participants are senior executives in Sedana Medical. The warrants were transferred under market terms. The transfer price was calculated with the aid of the Black & Scholes model by an independent institute. Each warrant entitles the holder to subscribe to one share in Sedana Medical AB at a subscription price equivalent to 130 percent of the issue price in the IPO, namely SEK 19.50. The warrants may be exercised during the period May 15, 2020 through January 31, 2021. The warrants are also subject to customary conditions for conversion in connection with new issues etc. If all of the warrants transferred to participants in the incentive program are exercised, the share capital in Sedana Medical AB (publ) will increase by around SEK 31,015 through the issue of 310,149 shares, equivalent to a dilution of around 1.6 percent based on the number of shares in the company on the closing date.

WARRANTS PROGRAM

As of December 31, 2018 Sedana Medical AB (publ) had 171 outstanding 2014/2019 series warrants issued at the extraordinary general meeting on June 24, 2014. The warrants entitle holders to subscribe to shares in Sedana Medical AB (publ) during the period from the warrant registration date through December 31, 2019. The warrants are subject to customary conversion conditions should the company make changes to the share capital and/or the number of shares through e.g. a new share issue, bonus issue, consolidation or a share split. Each warrant entitles the holder to subscribe to 4,000 shares. In all, the total number of outstanding warrants entitle subscriptions to 684,000 shares at a subscription price equivalent to SEK 2.5 per share. All of the 2014/2019 series warrants have been subscribed to by existing shareholders, related parties and senior executives in the Group. If all of the remaining 2014/2019 series warrants are subscribed to, Sedana Medical AB (publ)'s share capital will rise by SEK 68,400 through the issue of 684,000 shares equivalent to a dilution of 3.6 percent based on the number of shares in the company on the closing date.

Proposed appropriations of earnings

The following non-restricted reserves, accumulated earnings and parent company profits for the year are at the disposal of the AGM:

SEK thousand	
Share premium reserve	237,690,9
Losses carried forward	-49,438,7
Loss for the year	-3,755,2
Total unrestriced reserves	**184,497,0**

The Board proposes that available non-restricted equity be appropriated as follows:

SEK thousand	
Share premium reserve	237,690,9
Losses carried forward	-53,193,9
Total unrestriced reserves	**184,497,0**

Statement of changes in equity

Consolidated statement of changes in equity

SEK thousand	Share capital	Other Equity including result for the year	Total share-holders' equity
Opening balance January 1, 2017 according to balance sheet	217.0	1,044.8	1,261.8
Adjustments	0.0	0	0
Adjusted opening balance January 1, 2017	217.0	1,044.8	1,261.8
Changes in the carrying amounts recognised directly in equity			
New issue of shares	512.8	99,487.2	100,000.0
Bonus issue	651	-651.0	0.0
Conversion of convertibles	188.2	4,515.6	4,703.8
Conversion of share holder loan	61.4	11,903.7	11,965.1
Issue expenses	0.0	-12,310.8	-12,310.8
Overallotment option	76.9	14,923.1	15,000.0
Translation difference	0.0	-340.9	-340.9
	1,490.3	117,526.9	119,017.2
Net income	0.0	-3,875.7	-3,875.7
Total Equity December 31, 2017	1,707.3	114,696.0	116,403.3
Opening balance January 1, 2018	1,707.3	114,696.0	116,403.3
Changes in the carrying amounts recognised directly in equity			
New issue of shares	208.4	112,679.5	112,887.9
Issue expenses	0.0	-4,439.4	-4,439.4
Translation difference	0.0	-171.4	-171.4
	208.4	108,068.7	108,277
Net income	0.0	-6,869.1	-6,869.1
Total Equity 31 December, 2018	**1,915.7**	**215,895.6**	**217,811.3**

Statement of changes in equity

Parent company statement of changes in equity

SEK thousand	Share capital	Fund for capitalized development expenses	Share premium fund	Retained earnings including profit or loss for the period	Total shareholders' equity
Opening balance January 1, 2017 according to balance sheet	217.0	1,468.7	11,583.0	-3,958.8	9,309.9
Adjustments	0.0	0.0	0.0	0.0	0.0
Adjusted opening balance January 1, 2017	217.0	1,468.7	11,583.0	-3,958.8	9,309.9
Changes in the carrying amounts recognised directly in equity					
New issue of shares	512.8	0.0	99,487.2	0.0	100,000.0
Bonus issue	651.0	0.0	-651.0	0.0	0.0
Conversion of convertibles	188.2	0.0	4,515.6	0.0	4,703.8
Conversion of share holder loan	61.4	0.0	11,903.7	0.0	11,965.1
Issue expenses	0.0	0.0	-12,310.8	0.0	-12,310.8
Overallotment option	76.9	0.0	14,923.1	0.0	15,000.0
Translation difference	0.0	0.0	0.0	-94.8	-94.8
	1,490.3	0.0	117,867.8	-94.8	119,263.3
Reallocation between items in equity					
Allocations to funds for capitalized development expenses	0.0	4,934.1	0.0	-4,934.1	0.0
	0.0	4,934.1	0.0	-4,934.1	0.0
Net income	0.0	0.0	0.0	-4,626.7	-4,626.7
Total Equity December 31, 2017	1,707.3	6,402.8	129,450.8	-13,614.3	123,946.5
Opening balance January 1, 2018	1,707.3	6,402.8	129,450.8	-13,614.3	123,946.5
Changes in the carrying amounts recognised directly in equity					
New issue of shares	208.4	0.0	112,679.5	0.0	112,887.9
Issue expenses	0.0	0.0	-4,439.4	0.0	-4,439.4
Translation difference	0.0	0.0	0.0	70.3	70.3
	208.4	0.0	108,240.1	70.3	108,518.7
Reallocation between items in equity					
Allocations to funds for capitalized development expenses	0.0	35,894.7	0.0	-35,894.7	0.0
	0.0	35,894.7	0.0	-35,894.7	0.0
Net income	0.0	0.0	0.0	-3,755.2	-3,755.2
Total Equity 31 December, 2018	**1,915.7**	**42,297.4**	**237,690.9**	**-53,193.9**	**228,710.1**

OTHER FINANCIAL INFORMATION

Income Statement

Group

SEK thousand	Note	2018	2017
Revenues			
Net sales	4	57,896.2	40,427.7
Capitalized development expenses		0.0	1,290.9
Other operating income	6	1,474.5	1,571.7
		59,370.7	43,290.4
Operating cost and expenses			
Cost of goods sold		-14,999.7	-10,766.0
External expenses	7	-21,651.1	-16,825.4
Personnel expenses	8	-25,760.2	-16,194.6
Depreciation and amortisation		-4,005.9	-2,751.6
Other operating expenses	9	-1,192.0	-240.5
Operating income		-8,238.2	-3,487.8
Income from financial items			
Financial income	10	5,450.5	2,749.9
Financial expenses	11	-3,731.9	-3,863.2
Income after financial items		-6,519.6	-4,601.2
Income before taxes		-6,519.6	-4,601.2
Taxes	12	-349.4	725.5
Net Income		**-6,869.1**	**-3,875.7**

Balance Sheet

Group

SEK thousand	Note	Dec. 31, 2018	Dec. 31, 2017
ASSETS			
Fixed assets			
Intangible assets			
Capitalized development expenses	13	46,161.5	20,721.9
Concessions, patents, licenses, trademarks and similar	14	5,243.1	5,743.7
		51,404.5	26,465.6
Tangible assets			
Building and land	17	54.8	94.6
Machinery and equipment	15	4,128.5	2,824.8
Fixtures and tools	16	525.1	1,432.6
		4,708.4	4,352.1
Financial fixed assets			
Deferred tax receivables		1,590.9	1,459.6
Total fixed assets		**57,703.9**	**32,277.3**
Current assets	19		
Inventory		6,294.7	3,205.4
Advances to suppliers		6,294.7	3,205.4
Receivables		4,984.7	3,481.2
Trade receivables		349.1	406.4
Other current receivables		1,294.3	2,672.6
Deferred tax receivables		1,572.5	4,011.7
Prepaid expenses and accrued income		8,200.5	10,572.0
Cash and cash equivalents	25	159,350.7	85,321.6
Total current assets		173,845.9	99,099.0
TOTAL ASSETS		**231,549.8**	**131,376.3**

SEK thousand	Note	Dec. 31, 2018	Dec. 31, 2017
EQUITY AND LIABILITIES			
Equity			
Share capital		1,915.7	1,707.3
Other equity including net income for the period		215,895.6	114,696.0
Equity attributable to shareholders in parent company		217,811.3	116,403.3
Total equity		**217,811.3**	**116,403.3**
Long-term liabilities			
Liabilities to credit institutions	20	0.0	0.0
		0.0	0.0
Current liabilities			
Liabilities to credit institutions		0.0	3.6
Accounts payables		4,429.9	7,873.1
Tax liabilities		486.8	0.0
Other current liabilites	21	1,864.2	1,591.2
Accrued expenses and prepaid income	22	6,957.6	5,505.1
		13,738.5	14,973.0
TOTAL EQUITY AND LIABILITIES		**231,549.8**	**131,376.3**

Statement of cash flows

Group

SEK thousand	Note	2018	2017
Operations			
Operating income		-8,238.2	-3,487.8
Adjustment of non cash flow items		0.0	0.0
Depreciations and amortisations		5,661.3	2,751.6
Currency exchange rates differences		-385.4	-875.1
Provisions		0.0	-13.9
Other non cash flow items		97.0	195.4
		-2,865.3	-1,429.8
Received interest		2.7	0.7
Paid interest		-4.1	-2,591.5
Paid taxes		105.5	-211.3
Cash flow from operations before change in working capital		-2,761.1	-4,232.0
Cash flow from change in working capital			
Increase (-)/Decrease (+) of inventory		-3,079.0	1,331.1
Increase (-)/Decrease (+) of operating receivables		2,320.2	-6,248.6
Increase (+)/Decrease (-) of operating liabilities		-2,259.1	9,645.2
Cash flow from operations		-5,778.9	495.6
Investment activities			
Investment in intangible fixed assets		-25,101.5	-22,105.6
Investments in tangible fixed assets		-4,025.1	-3,776.4
Cash flow from investment activities		-29,126.5	-25,882.0
Financing activities			
New issue of shares		113,213.4	117,430.3
Issue expenses		-4,439.4	-12,310.8
Received loans		0.0	0.0
Amortisation of loans		0.0	-2,779.8
Cash flow from financing activities		108,774.0	102,339.7
Cash flow for the period		73,868.6	76,953.3
Liquid funds at the beginning of the period		85,321.6	8,296.4
Effects of exchange rate changes on cash		160.5	0.0
Translation difference in liquid funds		0.0	71.9
Liquid funds at the end of the period	25	**159,350.7**	**85,321.6**

Income statement

Parent company

SEK thousand	Note	2018	2017
Revenues			
Net sales	4,5	55,855.7	43,129.3
Capitalized development expenses		0.0	1,290.9
Other operating income	6	10,623.4	121.2
		66,479.1	44,541.5
Operating cost and expenses			
Cost of goods sold		-34,729.2	-26,460.1
External expenses	7	-16,828.9	-11,595.4
Personnel expenses	8	-18,676.1	-10,523.2
Depreciation and amortisation		-1,543.1	-1,175.7
Other operating expenses	9	-1,133.3	-226.1
Operating income		-6,431.4	-5,438.9
Income from financial items			
Result from securities and long term receivables		0.0	578.2
Financial income	10	6,445.7	2,749.0
Financial expenses	11	-3,721.4	-3,863.2
Income after financial items		-3,707.1	-5,974.9
Group contribution		0.0	1,348.2
Income before taxes		-3,707.1	-4,626.7
Taxes	12	-48.1	0.0
Net Income		**-3,755.2**	**-4,626.7**

Balance sheet

Parent company

SEK thousand	Note	Dec. 31, 2018	Dec. 31, 2017
ASSETS			
Fixed assets			
Intangible assets			
Capitalized development expenses	13,14	42,297.4	6,402.8
Concessions, patents, licenses, trademarks and similar		0.0	0.0
Tangible assets			
Machinery and equipment	15	2,413.6	2,824.8
Fixtures and tools	16	278.8	64.2
		2,692.4	2,889.0
Financial fixed assets			
Shares in group companies	18	50.0	50.0
Long term receivables in group companies		24,019.3	30,854.3
		24,069.3	30,904.3
Total fixed assets		69,059.1	40,196.1
Current assets			
Inventory			
Finished goods	19	9,227.2	6,108.6
Current receivables			
Trade receivables		4,380.5	3,160.9
Receivables in group companies		12,648.2	7,990.9
Tax receivables		349.1	332.5
Other current receivables		1,239.4	1,314.9
Prepaid expenses and accrued income		1,350.6	1,496.6
		19,967.8	14,295.9
Cash and cash equivalents	25	158,805.5	83,282.9
Total current assets		188,000.5	103,687.4
TOTAL ASSETS		**257,059.7**	**143,883.5**

SEK thousand	Note	Dec. 31, 2018	Dec. 31, 2017
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital		1,915.7	1,707.3
Fund for capitalized development expenses		42,297.4	6,402.8
Non restricted equity			
Share premium fund		237,690.9	129,450.8
Retained earnings		-49,438.7	-8,987.7
Profit or loss for the period		-3,755.2	-4,626.7
Total Equity		228,710.1	123,946.5
Liabilities to credit institutions	20	0.0	0.0
		0.0	0.0
Current liabilities			
Accounts payables		2,281.2	5,045.4
Liabilities to group companies		20,130.6	10,762.1
Other current liabilites	21	1,340.8	976.8
Accrued expenses and prepaid income	22	4,596.9	3,152.7
		28,349.6	19,937.0
TOTAL EQUITY AND LIABILITIES		**257,059.7**	**143,883.5**

Statement of cash flow

Parent company

SEK thousand	Not	2018	2017
Operations			
Operating income		-6,431.4	-5,438.9
Adjustment of non cash flow items			
Depreciations and amortisations		3,198.5	1,175.7
Currency exchange rates differences		164.6	-12.1
Provisions		0.0	0.0
Other non cash flow items		97.0	1,492.7
		-2,971.4	-2,782.6
Received interest		995.3	578.8
Paid interest		-4.0	-2,591.5
Paid taxes		0.0	-332.5
Cash flow from operations before change in working capital		-1,980.1	-5,127.9
Cash flow from change in working capital			
Increase (-)/Decrease (+) of inventory		-3,113.7	1,433.7
Increase (-)/Decrease (+) of operating receivables		-5,641.1	-8,481.8
Increase (+)/Decrease (-) of operating liabilities		8,328.0	7,182.1
Cash flow from operations		-2,406.9	-4,993.9
Investment activities			
Investment in intangible fixed assets		-35,754.7	-4,934.1
Investments in tangible fixed assets		-3,007.9	-2,688.9
Investments of financial assets		7,784.9	-14,204.8
Cash flow from investment activities		-30,977.7	-21,827.7
Financing activities			
New issue of shares		113,213.4	117,430.3
Issue expenses		-4,439.4	-12,310.8
Received loans		0.0	0.0
Amortisation of loans		0.0	-2,779.8
Cash flow from financing activities		108,774.0	102,339.7
Cash flow for the period		75,389.5	75,518.0
Liquid funds at the beginning of the period		83,282.9	7,711.1
Effects of exchange rate changes on cash		133.1	0.0
Translation difference in liquid funds		0.0	53.7
Liquid funds at the end of the period	25	**158,805.5**	**83,282.9**

NOTES

NOTE 1 GENERAL INFORMATION

Sedana Medical AB (publ), corporate ID number 556670–2519 is a public limited company domiciled in Sweden with its registered office in Danderyd, Sweden. The company's address is Vendevägen 87, SE 182 32 Danderyd, Sweden. The company's business objective is to develop, manufacture and sell medical devices. Sedana Medical AB (publ) is the parent company in the Sedana Medical Group.

NOTE 2 ACCOUNTING POLICIES

All amounts reported in SEK unless otherwise indicated. Accounting policies remain unchanged compared to previous years except for one departure from K3. As of Q3 2017, Sedana Medical AB (publ) does not gross report capitalized work for its own account under Other operating income, but reports development expenses net as a reduction of personnel and other expensed items.

General accounting policies
This Annual Report has been prepared in compliance with the Swedish Annual Accounts Act and the Swedish Accounting Standards Board's general recommendations BFNAR 2012:1 Annual accounts and consolidated financial statements (K3). Sedana Medical AB (publ), i.e. the parent company, and the Group apply the same accounting policies.

Consolidated financial statements
Subsidiaries
Subsidiaries are companies in which the parent company directly or indirectly holds more than 50 percent of the number of votes or has in some other way a controlling influence. Controlling influence means a right to determine a company's financial and operational strategies with the objective of gaining economic benefits. Business combinations are reported as a single unit of account. This means that the acquisition analysis is set up from the date the acquirer gains a controlling influence. As of this date, the acquirer and the acquired unit are regarded as a single accounting unit. Application of the single unit principle also means that all assets (including goodwill) and liabilities, as well as revenues and expenses, are taken into account in their entirety even in the case of part-owned subsidiaries. The cost of subsidiaries is calculated to the sum of fair value at the time of acquisition for the paid assets with additions for arising and acquired liabilities and the issuance of equity instruments, expenditures that are directly attributable to the business combination and any supplementary purchase price. With a few exceptions, fair value is determined in the acquisition analysis at the time identifiable assets, liabilities and non-controlling interests are acquired. Non-controlling interests are measured at fair value at the time of acquisition. The acquired company's revenues, expenses, identifiable assets, liabilities and any goodwill or negative goodwill are included in the consolidated financial statements from the moment of acquisition.

Elimination of transactions within the Group
Intra-group transactions, balance sheet items and unrealized gains and losses on transactions between Group companies are eliminated in their entirety.

Revenue
The inflow of economic benefits the company receives or will receive for its own account are reported as revenue. Revenue is measured at the fair value of what was received or will be received.

Sale of goods
When goods are sold, revenue is recognized upon delivery.

Interest, royalties and dividends
Revenue is recognized when the economic benefits associated with a transaction are likely to fall to the company and when the income can be calculated in a reliable manner.

Leasing – lessees
All leases are classified as operational leases. A financial lease is a lease under which the risks and benefits associated with owning an asset are in all material respects transferred from the lessor to the lessee. An operational lease is a lease that is not the financial lease.

Taxes
Tax on current year earnings in the income statement consists of current tax and deferred tax. Current tax is income tax for the current financial year in respect of taxable earnings for the year and that part of the previous financial year's income tax not yet reported. Deferred tax is income tax for taxable earnings in respect of future financial years as a result of earlier transactions or events.

Deferred tax is calculated on temporary differences. A temporary difference exists when the carrying amount of an asset or liability differs from the taxable value. Temporary differences are not taken into account in differences attributable to investments in subsidiaries, associated companies or joint ventures if the company is able to control the date for the reversal of the temporary difference and it is not evident that the temporary difference will be reversed in the foreseeable future. Nor are differences stemming from initial recognition of goodwill or initial recognition of an asset or liability temporary differences, unless the attributable transaction is a business combination or affects tax or reported earnings.

A deferred tax asset in respect of a loss carryforward or other future tax deductions is reported to the extent it is probable that the deductions can be settled against future tax surpluses.

In the consolidated financial statements, untaxed reserves are split into deferred tax liabilities and equity.

Valuation principles etc.
Assets, appropriations and liabilities have been appraised at cost unless otherwise indicated below.

Foreign currency
Items in foreign currency
Monetary items in foreign currency are translated at the spot rate on the closing date. Non-monetary items are not translated but entered at the acquisition date exchange rate. Transactions in foreign currencies are translated at the transaction date exchange rate.

Exchange rate differences arising when settling or translating monetary items are reported in the income statement of the financial year in which they arise either as an operational item or a financial item depending on the underlying business event.

Translation of foreign operations
Assets and liabilities, including goodwill and other group-related surplus and deficit values, are translated into the reporting currency at the closing date exchange rate. Revenues and expenses are translated at an exchange rate that constitutes an approximation of the actual exchange rate used (e.g. average exchange rate).

Exchange rate risk
Currency risk refers to the risk that the fair value or future cash flows will fluctuate as a result of changed currency rates. The company has both current and non-current receivables and liabilities in foreign currencies and is thus exposed to currency risk. In other words, exposure to currency risk stems principally from the translation of balance sheet items in foreign currency.

No hedging instruments are used.

Intangible assets
Expenditures for research and development
All expenditures that arise during the research phase are expensed as they arise.

When reporting development expenditures, the capitalization method is applied. This means expenditures arising during the development phase are reported as an asset once all of the conditions listed below are met:

- It is technically possible to complete the intangible fixed asset such that it can be used or sold.
- The intention is to complete the intangible fixed asset and use or sell it.
- Conditions exist that allow the use or sale of the intangible fixed asset.
- It is probable that the intangible fixed asset will generate future economic benefits
- Adequate requisite technical, economic and other resources exist to complete the development and to use or sell the intangible fixed asset.
- The expenditures attributable to the intangible fixed asset can be calculated in a reliable manner.

The cost includes personnel costs that have arisen during development work together with a suitable proportion of relevant expensed items and loan costs.

Other intangible assets
Other intangible assets acquired by the company are reported at cost less accumulated depreciations and impairment charges. Assets are depreciated in a straight-line over the assets' estimated useful life. Useful life is retested every balance sheet date. Projects in progress are not depreciated but are tested for impairment annually. Expenditures for internally generated goodwill and brands are expensed in the income statement as they arise.

Depreciations
Depreciation is calculated on a straight-line basis over the asset's calculated useful life. Depreciation is reported as an expense in the income statement. The following depreciation times are applied:

Internally developed intangible assets

	Group	Parent company
Expenditures for development and similar work brought forward	5 years	5 years

Property, plant and equipment
Property, plant and equipment are reported at cost less accumulated depreciation and impairment losses. In addition to the purchase price, cost can also include expenditures directly attributable to the acquisition.

Additional expenditures
Additional expenditures that meet the asset criterion are included in the asset's carrying amount. Expenditures in respect of running maintenance and repairs are expensed in the period in which they arise. The use of significant components has not been considered material for any of the tangible assets. Accordingly, no component depreciation has taken place.

Depreciations
Depreciation is calculated on a straight-line basis over the asset's calculated useful life as this reflects the expected pattern of consumption of the asset's future economic benefits. Depreciation is reported as an expense in the income statement. Useful life is retested on every balance sheet date.
The following depreciation times are applied:

Property, plant and equipment

	Group	Parent company
Machinery and other technical facilities	5–10 years	5 years
Equipment, tools, fixtures and fittings	5–10 years	5 years

Improvement expenditures on leased premises
Sedana Medical AB owns no real estate. Sometimes, major improvements are made to leased premises, and the improvements are capitalized. At its longest, the depreciation time on capitalized improvements coincides with the length of the lease on the premises, or 5 to 10 years.

Financial assets
Financial assets that are intended for long-term holding are reported at cost, and adjusted for currency effects where appropriate.

At least once per year, the asset is tested for the need to recognize impairment. Impairment takes place if the reduction in value is considered to be permanent. Impairment losses are reported under the income statement item Income from other securities and receivables held as non-current assets.

Inventories
Inventories are reported at the lower of cost or net realizable value. The risk of obsolescence is thus taken into account. Cost is calculated on the first-in first-out principal. In addition to purchase-related expenditures, cost also includes expenditures for bringing the goods to their current place and condition. The net realizable value has been calculated as the sales value less calculated selling expenses.

Offset of financial asset against financial liability
A financial asset and a financial liability are offset with a net amount in the balance sheet only when a legal right of offset exists and settlement with the net amount is intended to take place or when a contemporaneous disposal of the asset and liability are intended to take place.

Accounts receivable and other receivables
Receivables are reported as current assets with the exception of items with maturity dates more than twelve months from the closing date, which are reported as financial assets. Receivables are carried in the anticipated payment amounts less individually assessed doubtful receivables. Receivables that are interest free or which run with interest that deviates from market rates and have a maturity in excess of 12 months, are reported at a discounted present value and the change in the time value of money is reported as interest income in the income statement.

Loan liabilities and trade accounts payable
Loan liabilities and trade accounts payable are initially reported at cost less transaction expenses. If the reported amount differs from the amount that must be repaid on the due date, the difference is allocated over time as an interest expense over the loan's maturity period with the aid of the instrument's effective interest. By this means, the reported amount on the due date will coincide with the amount that must be repaid.

Provisions
Appropriations are reported when the Group has or can be assumed to have an obligation arising from an event and it is probable that expenditures will be required to settle the obligation. This is contingent upon the ability to make a reliable assessment of the amount that must be paid.

Employee benefits – pensions
The Group's pension plans for compensation on completion of employment are defined contribution plans. In defined contribution plans, the company pays fixed charges to a separate juridical entity. Once the charge is paid, the company has no further obligations.

Statement of cash flows
The statement of cash flows was prepared according to the indirect method. The reported cash flow includes only those transactions that entail receipts or payments. In addition to cash and bank balances, cash and cash equivalents also includes current investments that can easily be converted to a known amount and which are exposed to an insignificant risk of value fluctuation.

NOTE 3 SIGNIFICANT EVENTS AFTER THE CLOSE OF THE FINANCIAL YEAR

- Sedana Medical AB (publ) received approval for its planned pediatric studies from the Pediatric Committee of EMA, European Medicines Agency, (PDCO).
- Sedana Medical AB (publ) obtained the results of the interim analysis for the company's phase III study essential for registration, which shows fewer variations in effect than anticipated and will therefore only need to include a total of 300 patients instead of the initially estimated 550.
- Sedana Medical AB (publ) received positive message from the US Food and Drug Administration (FDA) during a pre-IND meeting regarding the combination registration of IsoConDa and AnaConDa in the US. Sedana Medical now has a clear view of measures that have to be taken in order to reach marketing authorization approval of both IsoConDa and AnaConDa in the US. The meeting with FDA also confirmed Sedana Medical's estimate of the time and cost of a US approval that is expected to occur in 2024.

NOTE 4 NETTOOMSÄTTNING

	Group		Parent company	
SEK thousand	2018	2017	2018	2017
Net sales				
Sedana Medical AB (publ)				
- Sales via Sweden	570.1		570.1	3652.5
- Branch in Germany	54,530.4	38225.7	54,530.4	38,899.5
- Branch in Spain	755.2	577.3	755.2	577.3
Sedana Medical Ltd, Ireland	80.0	213.3	0.0	0.0
Sedana Medical Sárl, France	1,960.5	1,411.4	0.0	
Total	**57,896.2**	**40,427.7**	**55,855.7**	**43,129.3**

NOTE 5 NET SALES

	Group		Parent company	
SEK thousand	2018	2017	2018	2017
Proportion of sales of goods relating to group companies	-	-	1,014.6	1,542.9
Proportion of sales of services relating to group companies	-	-	11,109.9	5,090.8
Proportion of purchases of goods relating to group companies	-	-	34,441.4	24,072.7

NOTE 6 OTHER OPERATING INCOME

	Group		Parent company	
SEK thousand	2018	2017	2018	2017
Foreign exchange rate gains on operating receivables / liabilities	1,325.8	159.5	1,323.9	56.8
Payment from employee stock options	0.0	1,412.2	0.0	0.0
Other	148.7	0.0	9,299.5	64.4
Total	**1,474.5**	**1,571.7**	**10,623.4**	**121.2**

NOTE 7 OPERATIONAL LEASING

	Group		Parent company	
SEK thousand	2018	2017	2018	2017
Minimum leasing fees	976.1	600.5	904.4	600.5
Total leasing costs	976.1	600.5	904.4	600.5
Contracted future minimum lease fees for non-cancellable contracts are due:				
Within a year	2,000.4	614.1	1,901.2	614.1
Between one and five years	1,454.4	454.6	1,303.1	454.6
Total	**3,454.8**	**1,068.7**	**3,204.3**	**1,068.7**

NOTE 8 EMPLOYEES, PERSONNEL EXPENSES AND BOARD RENUMERATION

Average number of employees

	2018			2017		
	Total	Women	Men	Total	Woman	Men
Parent Company						
Sweden	7.7	3.4	4.3	1.7	0.3	1.4
Germany	8.3	2.3	6.0	6.0	0.4	5.6
Spain	1.0	1.0	0.0	1.0	1.0	0.0
Total	**17.0**	**6.7**	**10.3**	**8.7**	**1.7**	**7.0**
Group						
Ireland	6.1	2.0	4.1	6.5	2.4	4.1
France	3.0	0.0	3.0	1.3	0.0	1.3
Total	**26.1**	**8.7**	**17.4**	**16.5**	**4.1**	**12.4**

Senior Executives

	2018			2017		
	Total	Women	Men	Total	Woman	Men
Board of Directors	6.0	1	5	5	0	5
CEO and senior executives	6.0	2	4	4	1	3

Salary and other remuneration and social security expenses, including pension costs to the CEO

	Group		Parent company	
SEK thousand	2018	2017	2018	2017
Salaries and other remuneration				
Chairman of the board Thomas Eklund	218.8	322.7	218.8	322.7
Board member Sten Gibeck	58.3	29.2	58.3	29.2
Board member Bengt Julander	58.3	29.2	58.3	29.2
Board member Ola Magnusson	58.3	693.9	58.3	693.9
Board member Michael Ryan	58.3	1,127.0	41.7	29.2
Board member Eva Walde	58.3	0.0	58.3	0.0
Former CEO, Michael Ryan	0.0	96.3	0.0	0.0
CEO, Christer Ahlberg	1,995.5	1,420.2	1,995.5	1,420.2
Total	2,505.9	3,718.4	2,489.3	2,524.2
Other senior executives	5,964.5	2,567.1	3,248.7	1,596.2
Other employees	15,516.2	7,867.1	10,334.4	4,617.6
Total	21,480.7	10,434.3	13,583.0	6,213.7
Total salaries and other remuneration	**23,986.6**	**14,152.7**	**16,072.3**	**8,737.9**
Social fees by law and agreement	4,911.8	2,376.8	3,669.1	1,671.5
Pensions to the CEO				
Of which for the former CEO	0.0	179.2	0.0	0.0
Of which for the current CEO	334.5	333.7	334.5	333.7
Total	**334.5**	**512.9**	**334.5**	**333.7**
Pensions to others				
Of which for other employees	1,032.8	0.0	884.1	0.0

NOTE 9 OTHER OPERATING EXPENSES

	Group		Parent company	
SEK thousand	2018	2017	2018	2017
Foreign exchange rate losses on operating receivables / liabilities	1,020.6	27.3	967.6	27.3
Other	171.4	213.2	165.7	198.8
Total	**1,192.0**	**240.5**	**1,133.3**	**226.1**

NOTE 10 FINANCIAL INCOME

	Group		Parent company	
SEK thousand	2018	2017	2018	2017
Interest income, Group companies	0.0	0.0	2.7	578.2
Interest income, Other	2.7	0.0	995.3	0.0
Foreign exchange gains	5,447.8	2,749.9	5,447.7	2,749.0
Total	**5,450.5**	**2,749.9**	**6,445.7**	**3,327.2**

NOTE 11 FINANCIAL EXPENSES

	Group		Parent company	
SEK thousand	2018	2017	2018	2017
Interest expenses	4.1	1,837.1	4.0	1,837.1
Foreign exchange losses	3,727.8	2,026.1	3,717.4	2,026.1
Other financial expenses	0.0	0.0	0.0	0.0
Total	**3,731.9**	**3,863.2**	**3,721.4**	**3,863.2**

NOTE 12 TAXES

	Group		Parent company	
SEK thousand	2018	2017	2018	2017
Current tax	1,067.6	0.0	48.1	0.0
Deferred tax	-718.2	-725.5	0.0	0.0
Total	**349.4**	**-725.5**	**48.1**	**0.0**

Reconcilliation of reported taxes

	Group		Parent company	
SEK thousand	2018	2017	2018	2017
Income before taxes	-6,519.6	-4,601.5	-3,707.1	-4,626.7
Tax at current tax rate 22%	-1,434.3	-1,012.3	-815.6	-1,017.9
Effect of foreign tax rates	-159.9	-225.4	7.8	9.0
Non-deductible costs	285.1	487.0	7.8	39.8
Non-taxable income	-161.8	-229.6	56.0	0.0
Tax	0.0	0.0	0.0	0.0
Current tax from previous years	839.0	345.6	0.0	0.0
Changes in loss carryforwards	981.3	-90.8	0.0	969.0
Other	0.0	0.0	799.9	0.0
Reported effective tax	**349.4**	**-725.5**	**0.0**	**0.0**

48,1

The Group has a deferred, unbalanced tax receivable of SEK 41 233 thousand of which SEK 35 275 thousand relates to the parent company.

NOTE 13 CAPITALIZED DEVELOPMENT EXPENSES

	Group		Parent company	
SEK thousand	2018	2017	2018	2017
Carrying amounts:				
- Opening cost	21,009.9	4,917.5	6,402.8	1,468.2
- In house development [1)]	24,454.8	1,290.9	35,894.6	1,290.9
- Acquisitions	0.0	14,455.7	0.0	3,643.7
- Translation differences	1,359.8	345.8	0.0	0.0
Closing cost	46,824.5	21,009.9	42,297.4	6,402.8
Carrying depreciations according to plan:				
- Opening depreciation	-288.0	0.0	0.0	0.0
- Amortization for the year	-362.0	-281.6	0.0	0.0
- Translation differences	-13.0	-6.4	0.0	0.0
Closing amortization	-663.0	-288.0	0.0	0
Carrying amount at the end of the period	**46,161.5**	**20,721.9**	**42,297.4**	**6,402.8**

[1)] In the parent company, internally developed assets during the year were acquired within the Group. As a result, a currency correction has been made in the Parent Company's cash flow statement. There is therefore a difference of SEK 139,9 thousand in acquisitions during the year in NOTE 13 compared with the same item in the Parent Company's cash flow statement.

NOTE 14 CONCESSIONS, PATENTS, LICENSES, TRADEMARKS AND SIMILAR

	Group		Parent company	
SEK thousand	2018	2017	2018	2017
Carrying amounts:				
- Opening cost	6,502.2	0.0	0.0	0.0
- Acquisitions	646.7	6,358.9	0.0	0.0
- Translation differences	238.4	143.3	0.0	0.0
Closing cost	7,387.3	6,502.2	0.0	0.0
Carrying depreciations according to plan:				
- Opening depreciation	-758.8	0.0	0.0	0.0
- Depreciation for the year	-1,350.4	-741.8	0.0	0.0
- Translation differences	-35.0	-16.7	0.0	0.0
Closing depreciation	-2,144.2	-758.5	0.0	0.0
Carrying amount at the end of the period	**5,243.1**	**5,743.7**	**0.0**	**0.0**

NOTE 15 MACHINERY AND EQUIPMENT

	Group		Parent company	
SEK thousand	2018	2017	2018	2017
Carrying amounts:				
- Opening cost	5,067.9	471.9	5,067.9	471.9
- Acquisitions	3,674.6	2624.5	2,818.8	2624.5
- Reclassifications	1,350.7	1873.4	-83.2	1873.4
- Translation differences	255.3	98.1	159.7	98.1
Closing cost	10,348.5	5,067.9	7,963.2	5,067.9
Carrying depreciations according to plan:				
- Opening depreciation	-1,524.4	-344.8	-1,524.4	-344.8
- Reclassifications		0.0	0.0	0.0
- Depreciation for the year	-2,184.9	-1,154.8	-1,515.2	-1,154.8
- Translation differences	-34.7	-24.8	-5.2	-24.8
Closing depreciation	-3,744.0	-1,524.4	-3,044.8	-1,524.4
Carrying write downs:				
- Opening write downs	-718.7	0.0	-718.7	0.0
-Omklassificeringar	28.8	0.0	0.0	0.0
- Write downs for the year	-1,752.4	-702.8	-1,752.4	-702.8
- Translation differences	-33.7	-15.9	-33.7	-15.9
Closing write downs	-2,476.0	-718.7	-2,504.8	-718.7
Carrying amount at the end of the period	**4,128.5**	**2,824.8**	**2,413.6**	**2,824.8**
Machinery and equipment under financial lease included with the following amount:	none	none	none	none

NOTE 16 FIXTURES AND TOOLS

	Group		Parent company	
SEK thousand	2018	2017	2018	2017
Carrying amounts:				
- Opening cost	2,596.1	1,485.1	273.3	207.0
- Acquisitions	320.4	1,044.9	159.0	60.1
- Reclassifications	-1,350.7	0.0	83.2	0.0
- Translation differences	163.0	66.1	9.2	6.2
Closing cost	1,728.8	2,596.1	524.7	273.3
Carrying depreciations according to plan:				
- Opening depreciation	-1,163.5	-574.0	-209.1	-185.6
- Reclassifications	28.8	0.0		0.0
- Depreciation for the year	-59.3	-559.9	-27.9	-17.7
- Translation differences	-9.7	-29.6	-8.9	-5.8
Closing depreciation	-1,203.7	-1,163.5	-245.9	-209.1
Carrying amount at the end of the period	**525.1**	**1,432.6**	**278.8**	**64.2**
Fixtures and tools under financial lease included with the following amount:	none	none	none	none

NOTE 17 UTLAYS ON LEASEHOLD PROPERTY

	Group		Parent company	
SEK thousand	2018	2017	2018	2017
Carrying amounts:				
- Opening cost	105.1	0.0	0.0	0.0
- Acquisitions	30.0	102.8	30.0	0.0
- Scrapping	-30.0	0.0	-30.0	0.0
- Translation differences	4.5	2.3	0.0	0.0
Closing cost	109.6	105.1	0.0	0.0
Carrying depreciations according to plan:				
- Opening depreciation	-10.5	0.0	0.0	0.0
- Depreciation for the year	-49.3	-10.3	-5.5	0.0
- Scrapping	5.5	0.0	5.5	0.0
- Translation differences	-0.5	-0.2	0.0	0.0
Closing depreciation	-54.8	-10.5	0.0	0.0
Carrying amount at the end of the period	**54.8**	**94.6**	**0.0**	**0.0**

NOTE 18 SHARES IN GROUP COMPANIES

	Group		Parent company	
SEK thousand	2018	2017	2018	2017
Carrying amounts:				
- Opening cost	0.0	0.0	50.0	0.0
- Acquisitions	0.0	0.0	0.0	50.0
Closing accumulated cost and carrying amount at the end of the period	**0.0**	**0.0**	**50.0**	**50.0**

Information of equity and result:

SEK thousand	Corp reg no /Reg office	Proportion of capital owned%	No of shares	Proportion of equity 2018	Proportion of equity 2017
Sedana Medical Ltd	IE551634 / Naas, Ireland	100	1	1,274.8	4,066.0
Sedana Medical Incentive AB	559109-8826/ Danderyd, Sweden	100	50,000	50.0	50.0
Sedana Medical Sàrl	809876865, Paris, France	100	2,000	-6,162.3	-5,443.0

SEK thousand	Corp reg no /Reg office	Proportion of the result 2018	Proportion of the result 2017
Sedana Medical Ltd	IE551634 / Naas, Ireland	-2,961.8	360.0
Sedana Medical Incentive AB	559109-8826/ Danderyd, Sweden	0.0	0.0
Sedana Medical Sàrl	809876865, Paris, France	-483.3	-2,149.0

SEK thousand	Corp reg no /Reg office	Kapialandel i %	Antal andelar	Booked value Dec. 31, 2018	Booked value Dec. 31, 2017
Shares directly owned by the parent company:					
Sedana Medical Ltd	IE551634 / Naas, Ireland	100	1	0.0	0.0
Sedana Medical Incentive AB	559109-8826/ Danderyd, Sweden	100	50,000	50.0	0.0
Shares owned by group companies:					
Sedana Medical Sàrl	809876865, Paris, France	100	2,000		

NOTE 19 INVENTORY

	Group		Parent company	
SEK thousand	2018	2017	2018	2017
Finished goods and goods for sale	6,294.7	3,205.4	9,227.2	6,108.6
Prepayments to suppliers	0.0	0.0	0.0	0.0
Total	**6,294.7**	**3,205.4**	**9,227.2**	**6,108.6**

NOTE 20 OVERDRAFT FACILITY

	Group		Parent company	
SEK thousand	2018	2017	2018	2017
Granted credit limit	500.0	500.0	500.0	500.0
Unutilized part	-500.0	-500.0	-500.0	-500.0
Total	**0.0**	**0.0**	**0.0**	**0.0**

NOTE 21 OTHER CURRENT LIABILITIES

	Group		Parent company	
SEK thousand	2018	2017	2018	2017
Loan from owners	0.0	0.0	0.0	0.0
Other liabilities	1,864.2	1,591.2	1,340.9	976.8
Total	**1,864.2**	**1,591.2**	**1,340.9**	**976.8**

NOTE 22 ACCRUED EXPENSES AND PREPAID INCOME

	Group		Parent company	
SEK thousand	2018	2017	2018	2017
Royalties	0.0	59.1	0.0	0.0
Salaries, social and other personnel expenses	3,663.6	3,471.4	3,663.4	1,426.7
Audit	245.3	453.5	169.3	453.5
Other	3,048.7	1,521.1	764.2	1,272.5
Total	**6,957.6**	**5,505.1**	**4,596.9**	**3,152.7**

NOTE 23 INFORMATION ON AUDITOR'S REMUNERATION

	Group		Parent company	
SEK thousand	2018	2017	2018	2017
R3 R Revsionsbyrå KB				
Audit assigment	201.7	218.8	201.7	218.8
Tax advice	0.0	0.0	0.0	0.0
Other services	0.0	60.6	0.0	60.6
Total	201.7	279.4	201.7	279.4
Other auditors				
Audit assignment	233.8	231.2	140.5	144.5
Tax advice	983.0	125.0	645.2	125.2
Other services	6.7	93.0	6.7	35.2
Total	1,223.5	449.2	792.4	304.9
Total	**1,425.2**	**728.6**	**994.1**	**584.3**

NOTE 24 CASH AND CASH EQUIVALENTS

	Group		Parent company	
SEK thousand	2018	2017	2018	2017
Bank deposits	159,350.7	85,321.6	158,805.5	83,282.9

NOTE 25 PLEDGED ASSETS AND CONTINGENT LIABILITIES

	Group		Parent company	
SEK thousand	2018	2017	2018	2017
For own liabilities and provisions				
Other liabilities to credit institutions				
Company mortage	0.0	0.0	0.0	0.0
	0.0	0.0	0.0	0.0
Other pledged assets and contingent liabilities				
Company mortage	0.0	0.0	0.0	0.0
	0.0	0.0	0.0	0.0
Total	**0.0**	**0.0**	**0.0**	**0.0**

NOTE 26 TRANSAKTIONER MED NÄRSTÅENDE

	2018		2017	
KSEK	Purchase of services	Purchase of goods	Purchase of services	Purchase of goods
Parent Company				
Eklund Consulting	0.0	0.0	161.0	0.0
Magiola AB	2.0	0.0	362.9	0.0
Total, Parent Company	**2.0**	**0.0**	**523.9**	**0.0**
Group				
Tecscan Ltd.	765.0	0.0	1,708.3	0.0
Lismed Ltd.	0.0	4,316.0	0.0	3,138.5
Total, Group	**767.0**	**4,316.0**	**2,232.2**	**3,138.5**

Eklund Konsulting is a company related to the Chairman of the Board Thomas Eklund.
Purchase of services from Eklund Consulting concern consulting services in relation to the IPO in first half year 2017.

Magiola AB is a company related to the board member Ola Magnusson.
Purchase of services from Magiola AB concern services for project leadership for IsoConDa clinical study.

Tecscan Ltd. is a company related to board member Michael Ryan.
Purchase of services from Tecscan Ltd. concern services for business development.

Lismed Ltd. Is a company related to the R&D manager Ron Farrell.
Purchase of goods from Lismed Ltd. concern the product Flurasorb and accessories which in turn are accessories to AnaConDa.

NOTE 27 DEFINITIONS OF KEY RATIOS

EBITDA margin:	Operating income before depreciations and amortisations (or Earnings Before Interest Taxes Depreciation and Amortisation) divided by Net sales.
Operating margin (EBIT-margin):	Opeerating income or Earnings Before Interest and Taxes divided by Net sales.
Net profit in % of Net sales:	Net profit devided by Net sales
Balance sheet total:	Total assets
Equity ratio:	Total equity plus 78% of untaxed reserves, divided by total assets.
Quick ratio:	Current assets excluding inventory divided by current liabilities.
Average number of employees:	Average number of full-time employees during the period.

The Board of Directors' and CEO's assurance

The Board hereby certifies that this annual report provides a true and fair overview of the Group's operations, financial position and earnings.
For a more detailed description of Sedana Medical's risks, we refer to the Group's prospectus submitted in connection with listing on Nasdaq First North.

Danderyd April 24, 2019

Thomas Eklund
Chairman of the Board

Sten Gibeck
Board member

Bengt Julander
Board member

Ola Magnusson
Board member

Michael Ryan
Board member

Eva Walde
Board member

Christer Ahlberg
CEO and Group President

My Audit Report was submitted on April 24, 2019.

Christina Kallin Sharpe
Authorized Public Accountant

AUDITOR'S REPORT

To the general meeting of the shareholders of Sedana Medical AB (publ)
Corporate identity number 556670-2519

Report on the annual accounts and consolidated accounts

Opinions

I have audited the annual accounts and consolidated accounts of Sedana Medical AB (publ) for the year 2018. The annual accounts and consolidated accounts of the company are included on pages 38-66 in this document.

In my opinion, the annual accounts and consolidated accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of parent company and the group as of 31 December 2018 and their financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts.

I therefore recommend that the general meeting of shareholders adopts the income statement and balance sheet for the parent company and the group.

Basis for Opinions

I conducted my audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. My responsibilities under those standards are further described in the "Auditor's Responsibilities" section. I am independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled my ethical responsibilities in accordance with these requirements.

I believe that the audit evidence I have obtained is sufficient and appropriate to provide a basis for my opinions.

Other Information than the annual accounts and consolidated accounts

The Board of Directors and the Managing Director are responsible for the other information. The other information comprises report Årsredovisning 18 (but does not include the annual accounts, consolidated accounts and my auditor's report thereon).

My opinion on the annual accounts and consolidated accounts does not cover this other information and I do not express any form of assurance conclusion regarding this other information.

In connection with my audit of the annual accounts and consolidated accounts, my responsibility is to read the information identified above and consider whether the information is materially inconsistent with the annual accounts and consolidated accounts. In this procedure I also take into account my knowledge otherwise obtained in the audit and assess whether the information otherwise appears to be materially misstated.

If I, based on the work performed concerning this information, conclude that there is a material misstatement of this other information, I am required to report that fact. I have nothing to report in this regard.

R3 Revisionsbyrå KB
Riddargatan 30 114 57 STOCKHOLM org.nr. 916503-3409
Tel: 08-555 108 00 Fax: 08-555 108 11
revision@r3.se www.r3.se

Responsibilities of the Board of Directors and the Managing Director

The Board of Directors and the Managing Director are responsible for the preparation of the annual accounts and consolidated accounts and that they give a fair presentation in accordance with the Annual Accounts Act. The board of Directors and the Managing Director are also responsible for such internal control as they determine is necessary to enable the preparation of annual accounts and consolidated accounts that are free from material misstatement, whether due to fraud or error.

In preparing the annual accounts and consolidated accounts, the Board of Directors and the Managing Director are responsible for the assessment of the company's and the group's ability to continue as a going concern. They disclose, as applicable, matters related to going concern and using the going concern basis of accounting. The going concern basis of accounting is however not applied if the Board of Directors and the Managing Director intends to liquidate the company, to cease operations, or has no realistic alternative but to do so.

Auditor's responsibility

My objectives are to obtain reasonable assurance about whether the annual accounts and consolidated accounts as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes my opinions. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts and consolidated accounts.

As part of an audit in accordance with ISAs, I exercise professional judgment and maintain professional scepticism throughout the audit. I also:

- Identify and assess the risks of material misstatement of the annual accounts and consolidated accounts, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for my opinions. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of the company's internal control relevant to my audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Board of Directors and the Managing Director.
- Conclude on the appropriateness of the Board of Directors' and the Managing Director's use of the going concern basis of accounting in preparing the annual accounts and consolidated accounts. I also draw a conclusion, based on the audit evidence obtained, as to whether any material uncertainty exists related to events or conditions that may cast significant doubt on the company's and the group's ability to continue as a going concern. If I conclude that a material uncertainty exists, I am required to draw attention in my auditor's report to the related disclosures in the annual accounts and consolidated accounts or, if such disclosures are inadequate, to modify my opinion about the annual accounts and consolidated accounts. My conclusions are based on the audit evidence obtained up to the date of my auditor's report. However, future events or conditions may cause a company and a group to cease to continue as a going concern.

• Evaluate the overall presentation, structure and content of the annual accounts and consolidated accounts, including the disclosures, and whether the annual accounts and consolidated accounts represent the underlying transactions and events in a manner that achieves fair presentation.

• Obtain sufficient and appropriate audit evidence regarding the financial information of the entities or business activities within the group to express an opinion on the consolidated accounts. I am responsible for the direction, supervision and performance of the group audit. I remain solely responsible for my opinions.

I must inform the Board of Directors of, among other matters, the planned scope and timing of the audit. I must also inform of significant audit findings during my audit, including any significant deficiencies in internal control that I identified.

Report on other legal and regulatory requirements

Opinions

In addition to my audit of the annual accounts and consolidated accounts, I have also audited the administration of the Board of Directors and the Managing Director of Sedana Medical AB (publ) for the year 2018 and the proposed appropriations of the company's profit or loss.

I recommend to the general meeting of shareholders that the profit be appropriated in accordance with the proposal in the statutory administration report and that the members of the Board of Directors and the Managing Director be discharged from liability for the financial year.

Basis for Opinions

I conducted the audit in accordance with generally accepted auditing standards in Sweden. My responsibilities under those standards are further described in the "Auditor's Responsibilities" section. I am independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled my ethical responsibilities in accordance with these requirements.

I believe that the audit evidence I have obtained is sufficient and appropriate to provide a basis for my opinions.

Responsibilities of the Board of Directors and the Managing Director

The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company's and the group's type of operations, size and risks place on the size of the parent company's and the group's equity, consolidation requirements, liquidity and position in general.

The Board of Directors is responsible for the company's organization and the administration of the company's affairs. This includes among other things continuous assessment of the company's and the group's financial situation and ensuring that the company's organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner. The Managing Director shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfill the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

• Evaluate the overall presentation, structure and content of the annual accounts and consolidated accounts, including the disclosures, and whether the annual accounts and consolidated accounts represent the underlying transactions and events in a manner that achieves fair presentation.

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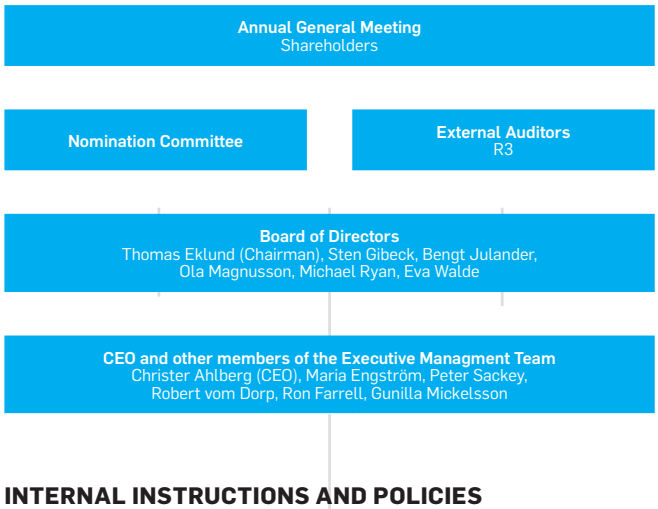
CORPORATE GOVERNANCE

LEGISLATION AND THE ARTICLES OF INCORPORATION

Sedana Medical is a Swedish public limited liability company governed by Swedish law, primarily the Swedish Companies Act (2005:551) and the Swedish Annual Accounts Act (1995:1554). The company's shares were listed on the Nasdaq First North on June 21, 2017. The company has subsequently applied Nasdaq First North's regulations. In addition to legislation and Nasdaq First North's regulations, the company's articles of incorporation and its internal guidelines for corporate governance form the basis for said governance. The articles of incorporation set forth such things as the company's registered office, the focus of operations, limitations to share capital and the number of shares, and conditions for participating in the shareholders' meetings. The latest submitted and registered articles of incorporation were adopted at the AGM of May 19, 2017.

The chart below shows Sedana Medical's corporate governance model and how the various departments function.



INTERNAL INSTRUCTIONS AND POLICIES OF IMPORTANCE FOR CORPORATE GOVERNANCE

Articles of incorporation

- The Board's rules of procedure and CEO instructions
- Policy for financial reporting
- Authorization instructions
- Information policy
- Insider policy
- Insider policy
- IT policy
- Conduct policy

EXTERNAL REGULATIONS THAT AFFECT THE ARTICLES OF INCORPORATION

- Swedish Companies Act
- Accounting regulations
- Nasdaq First North regulations

THE SWEDISH CODE OF CORPORATE GOVERNANCE

The Swedish Code of Corporate Governance (the Code) sets forth a higher standard of good corporate governance than the minimum requirements of the Swedish Companies Act and must be applied by companies whose shares are admitted for trading on a regulated market in Sweden. The Code is not currently binding on companies whose shares are listed on Nasdaq First North, and thus are not binding on the company. The company does not follow the Code nor does it meet its requirements.

ANNUAL GENERAL MEETING

Shareholder influence in the company is exercised at shareholders' meetings which, in accordance with the Swedish Companies Act, is the company's highest decision-making body. As the company's highest decision-making body, a shareholders' meeting can take decisions about all matters in the company that do not constitute another company body's exclusive area of competence. A shareholders' meeting has thus a superior role in relation to the company's Board of Directors and the CEO. Notices to attend, minutes and communiqués from shareholders' meetings will be kept available on the company's website. At the general shareholders' meeting (annual general meeting), which under the Swedish Companies Act must be held within six months from the end of each financial year, resolutions must be made concerning the approval of the income statement and balance sheet, allocations concerning the company's profit or loss, discharging the Board of Directors and Chief Executive Officer from liability, election of Board members and auditors, and compensation to the Board and auditor. Shareholders may also pass resolutions at shareholders' meetings on other essential company matters such as changes to the company's articles of incorporation, and any new share issues etc. If the board finds reason to convene a shareholders' meeting before the next general shareholders' meeting, or if a company auditor or owner of a minimum of one tenth of all shares in the company so requests in writing, the Board must convene an extraordinary shareholders' meeting. Notice to attend the AGM and extraordinary shareholders' meeting where changes to the articles of incorporation will be addressed, must take place at the earliest six weeks and

at the latest four weeks before the meeting. Notice to attend other extraordinary shareholders' meetings must take place at the earliest six weeks and at the latest three weeks before the meeting. Notice to attend is given through the Official Swedish Gazette (Post- och Inrikes Tidningar) and the company's website. At the same time, an announcement that notice has been given must be placed in the Swedish business daily, Dagens Industri. To participate in a shareholders' meeting, shareholders must be registered in the share ledger maintained by Euroclear Sweden AB on a record date that falls no later than five working days before the meeting, and give notice of their intention to participate in the meeting by no later than the day indicated in the notice to attend. This day may not be a Saturday, Sunday, public holiday, Midsummer's Eve, Christmas Eve or New Year's Eve and may not fall earlier than five working days before the meeting. Shareholders may participate in the shareholders' meeting in person or be represented by proxy or alternatively by no more than two persons. There are usually opportunities for shareholders to register their participation in the meeting in a number of ways in accordance with instructions in the notice to attend. Shareholders who wish to have a matter addressed at the meeting must submit a request in writing to the company's Board. Such a request must usually reach the Board no later than seven weeks before the shareholders' meeting. In order to determine who has the right to participate and vote at shareholders' meetings, Euroclear Sweden AB, upon company request, must provide the company with a list of all shareholders as of the record date in connection with each shareholders' meeting. Shareholders whose shares are registered in the name of a nominee or trustee must instruct the nominee to temporarily register the shares in the shareholder's own name (voting right registration) in order to be eligible to participate and vote their shares at shareholders' meetings. Such registration must be completed no later than the applicable record date and cease to be valid after the record date. Shareholders whose shares are directly registered in an account in the Euroclear system will be included automatically in the list of shareholders.

NOMINATION COMMITTEE

The company's AGM of May 19, 2017 resolved to adopt the following principles for appointment and instructions in respect of nominations prior to the 2018 AGM. The following principles and instructions apply until any resolution changing them is adopted by the AGM. The nomination committee must comprise the Chairman of the Board and three members appointed by the three biggest shareholders in terms of votes at the end of the third quarter of the year concerned. Every year, the Chairman of the Board must contact the shareholders who are eligible to appoint members. If any of the shareholders chooses to waive his right to appoint a member to the nomination committee, the right is transferred to the next biggest shareholder in terms of votes, and so forth. However, no more than five additional shareholders must be contacted, unless the Chairman of the Board finds that special reasons pertain. When shareholders are contacted regarding appointment of members to the nomination committee, the Chairman of the Board must establish the necessary rules such as the latest response date etc. The names of the nomination committee members and the names of the shareholders appointing the members must be published no later than six months before the AGM. The nomination committee appoints its own chairman internally. The Chairman of the Board may not be the chairman of the nomination committee. If a member leaves the nomination committee before his work is completed, and the committee considers a replacement necessary, the replacement must be appointed by the same shareholder who appointed the retired member or, if said shareholder no longer belongs to the three biggest shareholders in terms of votes, by the shareholder who belongs to this group. If a shareholder, having appointed a certain member, has significantly reduced his holding in the company, and the nomination committee does not find it inappropriate in view of the possible need for continuity for the forthcoming shareholder's meeting, the member must leave the nomination committee and the committee must offer the biggest shareholder who has not appointed a member to the committee the opportunity to appoint a new member. Nomination committee members do not receive remuneration from the company. Any expenditures arising in connection with the nomination committee's work must be paid by the company on the condition that they are approved by the Chairman of the Board.

Board of Directors

THE BOARD'S ASSIGNMENTS

In relation to the shareholders' meeting, the Board of Directors is the company's second highest decision-making body. The Board is also the company's highest executive body and represents the company. Furthermore, under the Swedish Companies Act, the Board is responsible for the company's organization, the administration of its affairs, the ongoing assessment of the company's and Group's financial situation, and ensuring that the company's organization is designed such that the company's

accounting, asset management and the financial circumstances in other respects are satisfactorily controlled. The Chairman of the Board bears special responsibility for leading the work of the Board and making sure the Board fulfills its statutory duties. The Board's assignments include setting forth the company's overall goals and strategies, supervising major investments, ensuring the satisfactory control of the company's compliance with legislation and other regulations that apply to the company's operations, and the company's compliance with internal policy documents. The Board's assignments also include ensuring that the company's disclosures to the market and investors are characterized by openness and that they are accurate, relevant and reliable. The Board also appoints, evaluates and if necessary dismisses the company's Chief Executive Officer. In accordance with the Swedish Companies Act, the Board has set forth written rules of procedure for its work that are evaluated, updated and re-adopted annually. The Board meets regularly according to a schedule set forth in the rules of procedure that includes certain fixed agenda items and other agenda items as necessary.

COMPOSITION OF THE BOARD OF DIRECTORS

According to the company's articles of incorporation, the Board must comprise at least three (3) and no more than six (6) members with a maximum of three (3) alternates. Members are elected annually at a general shareholders' meeting (annual general meeting) up until the end of the next general shareholders' meeting. There is no limit for how long a member may sit on the Board. As of the financial year's closing date, the company's Board consisted of six members.

CHAIRMAN OF THE BOARD

The Chairman of the Board is tasked with leading the work of the Board and ensuring that it is carried out effectively and that the Board fulfills its obligations. Through his contacts with the CEO, the Chairman must observe the company's development and make sure that the CEO constantly provides Board members with the information they need to monitor the company's position, financial planning and development. Furthermore, the Chairman must consult with the CEO on strategic matters and check that the Board's decisions are effectively executed The Chairman of the Board is responsible for contacts with shareholders on ownership matters and for conveying the views of the owners to the Board. The Chairman does not take part in the operational work of the Board, and nor is he part of company management.

THE WORK OF THE BOARD

The Board follows written rules of procedure that must be reviewed annually and adopted at the statutory board meeting. Among other things, the rules of procedure govern the Board's functions, assignments, decision-making process and order of business, and the Chairman's assignments and the allocation of work between the Board and the CEO. Instructions regarding financial reporting and the CEO instructions are also set forth in connection with the statutory board meeting. In parallel with board meetings, the Chairman of the Board and the CEO maintain a dialogue concerning the management of the company. The Board meets according to an annual timetable, and must hold at least five scheduled board meetings between each AGM.

	Attendance no. of meetings 2017 post AGM	Board fees decided at the Annual General Meeting 2017	Independent in relation to:	
	Board meetings (18)	KSEK	The Group	Owners
Chairman of the board				
Thomas Eklund	18	225	Yes	Yes
Board member				
Sten Gibeck	18	50	Yes	Yes
Bengt Julander	18	50	Yes	No
Ola Magnusson	18	50	Yes	Yes
Michael Ryan	17	50	Yes	Yes
Eva Walde	12	100	Yes	Yes

The CEO and other senior executives

The company's CEO is subordinate to the Board and, under the provisions of the Swedish Companies Act, takes care of day-to-day company administration in compliance with the Board's guidelines and instructions. Measures that, with regard to the scope and nature of the Company's operations, are of an unusual nature or of great significance do not fall within day-to-day administration and must as a rule be prepared and presented to the Board for a decision. The company's CEO must also take necessary measures to ensure that the company's accounting records are completed in compliance with the law and that asset management is performed in a satisfactory manner. The allocation of work between the Board and the CEO is described in the Board's rules of procedure and the CEO instructions. The Board

continually evaluates the Chief Executive Officer's work. Christer Ahlberg was the company's CEO on the closing date. Otherwise, Sedana Medical's company management consisted of Chief Financial Officer Maria Engström, Chief Medical Officer Peter Sackey, Head of Sales Robert vom Dorp, Head of R&D Ron Farrell and Head of Marketing Gunilla Mickelsson.

Internal Control and Audit

Under the Swedish Companies Act, the Board is responsible for the company's organization, the administration of its affairs, the ongoing assessment of the company's and Group's financial situation, and ensuring that the company's organization is designed such that company's accounting, asset management and the financial circumstances in other respects are satisfactorily controlled. The rules of procedure established by the Board include instructions for internal financial reporting. All interim reports and press releases are published on the company's website (www.sedanamedical.com) as soon as they are released. In its capacity as a public company, the company is required to have at least one auditor for auditing the company's and consolidated annual accounts and accounting records and the administration of the Board and the Chief Executive Officer. The audit must be as detailed and comprehensive as generally accepted auditing standards require. The company's auditors are elected by a general shareholders' meeting in compliance with the Swedish Companies Act. Accordingly, an auditor in a Swedish limited company is engaged by, and reports to, the shareholders' meeting and may not be guided in her work by the Board or any other senior executive. According to the company's articles of incorporation, the shareholders' meeting must appoint at least one (1) and no more than two (2) auditors with no more than two (2) alternate auditors. The company's current auditor is Christina Kallin Sharpe.

Compensation to board members, senior executives and auditor

Compensation to Sedana Medical's board members is resolved by the shareholders' meeting. The AGM of May 21, 2018 passed a resolution concerning annual board fees in the amount of SEK 225,000 to the chairman, and SEK 100,000 to board member Eva Walde and SEK 50,000 each to the other board members. Compensation to senior executives who are employees may consist of a basic salary, variable remunerations, pension and other benefits. In addition to his monthly salary, CEO Christer Ahlberg has the right to an annual bonus amounting to no more than six monthly salaries. The bonus is linked to the company's sales, its operating earnings before interest, tax, depreciations, impairments and goodwill depreciations and performance in relation to objectives. In addition to statutory pensions, the company sets aside an amount equivalent to 25 percent of the CEO's fixed monthly salary to an occupational pension scheme determined by the CEO. The period of notice for termination is 6 months on the part of the CEO and 12 months on the part of the company. Otherwise the CEO is subject to customary employment conditions containing rules on confidentiality, non-competition and non-solicitation. The total compensation to the auditor for the financial year 2018 amounted to SEK 221.7 thousand. Compensation to the company's auditor is paid according to invoice.

BOARD OF DIRECTORS

Thomas Eklund

Chairman of the Board

Born: 1967

Position: Member of the Board and Chairman of the Board at Sedana Medical since 2014.

Education and work experience: Thomas has an MBA from the Stockholm School of Economics. Around 25 years' experience from leading positions in e.g. the banking, life sciences and healthcare sectors. CEO of Investor Growth Capital (now Patricia Industries) from 2002 through 2012, and investor owned private equity company focused on longterm investments in technology, healthcare and industry. Former member of the boards of life science companies such as Swedish Orphan International AB (Chairman) and Carmel Pharma AB.

Other current assignments: Chairman of the boards of Biotage AB, Calliditas Theraputics AB, Itrim Holding AB and Moberg Pharma AB (publ). Member of the boards of Boule Diagnostics AB, Excillum Aktiebolag, Impilo No 4 Holding II AB, Memira Holding AB, Neoventa Medical AB, Rodebjer Form AB, SciBase Holding AB (publ), Surgical Science Sweden AB, Swedencare AB (publ) and a board member in smaller subsidiaries of these companies or small family companies.

Shareholding in Sedana Medical: 474,156 shares via Eklund konsulting AB**.**

Independent in relation to the company, its management and the company's major shareholders.

Sten Gibeck

Board member

Born: 1943

Position: Member of the Board at Sedana Medical since 2005. Former Board Chairman.

Education and work experience: Sten holds a higher business administration qualification from Sveriges Kontorist-förening. Former owner and CEO of the medical device company Louis Gibeck AB during its journey from being a small distribution company to achieving a marketleading position in its field in e.g. Germany, France, Japan and the USA. For a number of years at the end of the 1990s, Louis Gibeck AB was traded on the OTC list in Stockholm before the company was bought out by Hudson Respiratory Care Inc., in which Sten Gibeck was a member of the board 1999–2004.

Other current assignments: –

Shareholding in Sedana Medical: 1,605,744 shares.

Independent in relation to the company, its management and the company's major shareholders.

Bengt Julander

Board member

Born: 1953

Position: Member of the Board at Sedana Medical since 2011.

Education and work experience: Bengt is a qualified pharmacist, M. Sc. From Uppsala University. Owner and board member of Linc AB, which invests in companies in the drug and medical device segment. Operational, board and ownership experience from the industry.

Other current assignments: Chairman of the Board of Knil AB. Member of the boards of Calliditas Therapeutics AB, Cronhamn Invest AB, Linc AB, Livland Skog AB, Medivir Aktiebolag, nWise AB, ProEquo AB, Stille AB, Swevet AB and Swevet Holding AB. Alternate board member of Eriksbergskliniken AB and member and alternate member of the boards of small subsidiaries to these companies or small family companies.

Shareholding in Sedana Medical: 1,901,901 shares via Linc AB.

Independent in relation to the company, its management but not to major shareholders.

Ola Magnusson

Board member

Born: 1948

Position: Member of the Board at Sedana Medical since 2005. Previously CEO of Sedana Medical (2005–2011).

Education and work experience: Ola is a technical college graduate with a focus on chemistry from Gothenburg Technical College. Approaching 30 years' experience from the pharmaceutical industry and 20 years' experience from the medical devices sector, mainly in sales and marketing and company management. Former CEO of Louis Gibeck AB and responsible for the company's listing on the OTC list in Stockholm. Former CEO of Hudson RCI AB following its acquisition of Louis Gibeck AB. Worked in the Pharmacia group in the USA twice during the 1980s and 90s. Founded Sedana Medical 2005 and acted as CEO up until 2011.

Other current assignments: Chairman of the boards of Eataway AB and Transcutan AB. Member of the boards of Hammarplast Medical Aktiebolag, Miris Holding AB (publ) and subsidiaries to these companies or small family companies.

Shareholding in Sedana Medical: 1,296,000 shares via Magiola Consulting AB.

Independent in relation to the company, its management and the company's major shareholders.

Michael Ryan

Board member

Born: 1957

Position: Member of the Board at Sedana Medical since 2005. Previously CEO of Sedana Medical (2011–2017).

Education and work experience: Michael holds a Master of Industrial Engineering (1st Class Honours) from University College Dublin. Before becoming CEO of Sedana Medical in 2011, Michael was the main shareholder and CEO of Artema Medical AB until the company was acquired in 2008. He was also the owner of Excal AB and has held senior positions in technology companies in Ireland and Sweden for more than 25 years.

Other current assignments: CEO and board member of TecScan Ireland Ltd. Member of the boards of Anades Ltd, Irrus Investment Ltd, Salmur Ltd and Venn Life Sciences Ltd.

Shareholding in Sedana Medical: 1,068,083 shares via Anades Ltd. and 35 warrants that entitle subscription to 140,000 shares.

Independent in relation to the company, its management and the company's major shareholders.

Eva Walde

Board member

Born: 1963

Position: Member of the Board at Sedana Medical since 2018.

Education and work experience: Eva has an MBA from the School of Business, Economics and Law in Gothenburg, Sweden. More than 20 years' experience from the pharmaceutical industry and the medical devices sector, mainly in sales, marketing and company management. Previously VP Commercial Opera-tions, International Region at Phadia/ThermoFisher Scientific and Strategic Affairs Director at Johnson & Johnson Nordic AB, Medical Device and Head of Strategic development at Pfizer AB.

Other current assignments: Works as a management consultant and is the CEO and member of the board of her own company Movits Consulting AB, and is an alternate board member of Finnson & Partners AB.

S**hareholding in Sedana Medical:** 3,200 shares.

Independent in relation to the company, its management and the company's major shareholders.

ORGANIZATION AND COMPANY MANAGEMENT

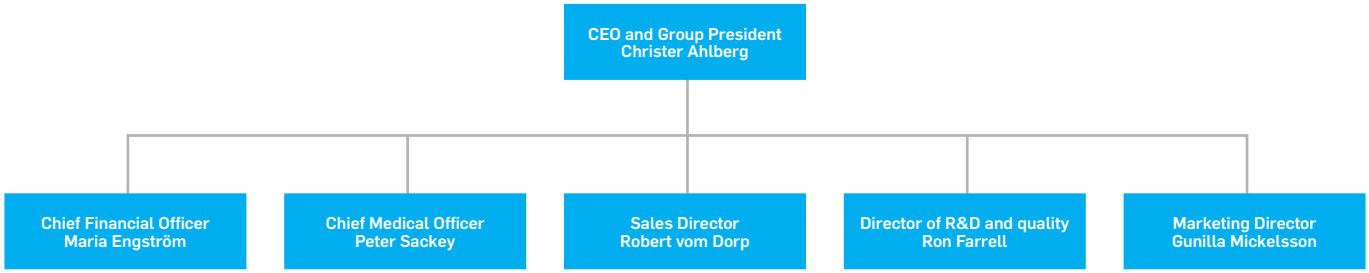
Organization

Sedana Medical has personnel with a broad background and experience in company management, marketing, sales, production and R&D from both the pharmaceutical and medical device industries.

Sedana Medical's head office is in Danderyd, Stockholm, while research and development is located in Ireland. The Group also has a number of product specialists employed in Germany, France, the Nordics and Spain. During 2018, the average number of employees was 26.2. Through its long-term, determined efforts, the Group has created a strong organization that attracts experienced personnel to the company. In the years ahead, Sedana Medical will increase the number of employees in line with Group growth and thus create an organization well prepared to introduce IsoConDa to the market. To achieve its operational and financial objectives, Sedana Medical will pay great attention to strengthening its product specialist organization on current and future markets and boosting pharmaceutical skills throughout the organization.

COMPANY MANAGEMENT

The Group's management group comprises CEO Christer Ahlberg, CFO Maria Engström, CMO Christer Ahlberg, Head of R&D Ron Farrell, Head of sales Robert vom Dorp and Head of marketing Gunilla Mickelsson.



Christer Ahlberg

CEO and Group President

Born: 1971

Position: Chief Executive Officer and Group President of Sedana Medical since February 2017.

Education and work experience: Christer has an MBA from Örebro University.
Previous experience from the pharmaceutical industry, lately as CEO of the Unimedic Group (2010–2016) and CEO of Eisai AB (2005–2010) as well as more than 10 years' experience from managerial positions in sales, marketing and market access in the pharmaceutical industry with such companies as AstraZeneca, Meda and Wyeth. Member of the board of PharmaControl MQL AB.

Other current assignments: Member of the boards of Anthrop Pharmaceuticals AB and Sedana Medical Ltd. CEO and member of the board of Sedana Medical SARL. CEOs and alternate board member of Waxholm by the sea aktiebolag. Alternate board member of Sedana Medical Incentive AB.

Shareholding in Sedana Medical: 230,000 shares and 184,200 warrants that entitle subscription to 184,200 shares.

Maria Engström

Chief Financial Officer

Born: 1972

Position: CFO of Sedana Medical since February 2017.

Education and work experience: Maria has an MBA from Stockholm University.
Previously Head of Cross Pharma AB (2015–2016) and Head of Business Control at Medivir AB (2012–2014). More than 15 years' experience from positions as CFO, Head of Business Control and controller at Biovitrum, Bristol Myers Squibb and Ericsson.

Other current assignments: Member of the board of FAYSIT – Finance At Your Service In Tyresö AB. Alternate board member of UHT Förvaltning AB.

Shareholding in Sedana Medical: 3,850 shares and 60,782 warrants that entitle subscription to 60,782 shares via FAYSIT – Finance At Your Service In Tyresö AB.

Peter Sackey

Chief Medical Officer

Born: 1971

Position: Chief Medical Officer of Sedana Medical since January 2018.

Education and work experience: Peter took his MD degree in 1997 at Karolinska University Hospital.
For just over 20 years he practiced perioperative medicine and intensive care at Karolinska University Hos-pital and has European degrees in anesthetics (DESA) and intensive care (EDIC). He defended his doctoral thesis – Isoflurane Sedation in Intensive Care Unit Patients – at Karolinska University Hospital in 2006.
Peter is an associate professor at Karolinska University Hospital and has tutored many doctoral students and conducted research in intensive care.

Previous positions: Chief physician, head of the Neuro-intensive care function unit, Perioperative Medicine and intensive care at the Karolinska University Hospital, Stockholm.

Other current assignments: Associate professor, Department of Physiology and Pharmacology, Karolinska University Hospital.

Shareholding in Sedana Medical: 975 shares and 65,167 options, equivalent to 65,167 shares.

Ron Farrell

Director of R&D and quality

Born: 1956

Position: Director of R&D and quality at Sedana Medical since 2011. CEO of Sedana Medical Ltd.

Education and work experience: Ron has a graduateship of the Plastics and Rubber Institute of London (GPRI). 37 years' experience in the manufacturing industry in various managerial positions in companies such as Oral-B Laboratories, Gilette, Vistakon, Tech Group, Artema Medical and Kayfoam Woolfson. Active principally in engineering, quality assurance, supply chain, development and operational management in respect of factories.

Other current assignments: Member of the boards of Lismed Ltd. And Sedana Medical Ltd.

Shareholding in Sedana Medical: 731,062 shares and 55 warrants that entitle subscription to a total of 220,000 shares.

Robert vom Dorp

Sales Director

Born: 1970

Position: Sales director for Sedana Medical since 2010, employed since 2005.

Education and work experience: Robert has an MBA in economics from the University of Applied Sciences at Hochschule Koblenz. He has also studied industrial organization. Has worked in medical device sales since 2001, and was previously an account manager for products for anesthesia, ventilation and intensive care at Hudson RCI and Teleflex Medical. Responsible for marketing, strategy, sales and personnel at Sedana Medical's sales office (branch) in Germany. Also responsible for dealers in Austria and Switzerland. Previously consultant for a company that issued ISO certificates to hospitals.

Other current assignments: –

Shareholding in Sedana Medical: 7,500 shares and 26 warrants that entitle subscription to a total of 104,000 shares.

Gunilla Mickelsson

Marketing Director

Born: 1971

Position: Marketing Director for Sedana Medical since October 2018.

Education and work experience: Gunilla has an MBA from Örebro University. She was previously Head of Global Marketing, Specialty Care unit at Swedish Orphan Biovitrum (SOBI), and before that Sr Director Commercial Strategies and Alliance Management at Sobi Partner Products.

Previous positions: Gunilla has more than 20 years' experience from various types of executive commercial roles within the pharmaceutical industry in companies such as AstraZeneca, Meda, Wyeth and Pfizer.

Other current assignments: Member of the board of Kapfovaltre AB.

Shareholding in Sedana Medical: 1500 shares.

ANNUAL GENERAL MEETING

Sedana Medical's AGM will be held at 16:00 on May 28, 2019, on the premises of Erik Penser, Apelbergsgatan 27, Stockholm. To be eligible to participate in the meeting, shareholders must be registered in the share ledger maintained by Euroclear Sweden AB by May 24, 2019. In good time before this date, shareholders who have registered their shares in the name of a nominee or trustee should, through the offices of the nominee or trustee, temporarily register the shares in their own name to be eligible to participate. Registration for the meeting begins at 15:30.

CERTIFIED ADVISER

Erik Penser Bank is certified advisor for Sedana Medical AB (Publ).

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PUBLICATIONS CALENDAR

Interim report, first quarter 2019	May 8, 2012
Interim report, second quarter 2018	August 22, 2019
Interim report, third quarter 2018	November 13, 2019.

SEDANAMEDICAL

Pioneering volatile anaesthetic delivery

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